

US3362083 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3362083

Form: Participant Creation

Data signed: (b) (4) 24 Apr 2021 00:10:12

Generated On: 11 Aug 2021 22:35:02

[Participant ID](#)

US3362083

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

US3362083

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 10 Apr 2021 00:15:34

Generated On: 11 Aug 2021 22:35:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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) 10 Apr 2021 00:15:34

Generated On: 11 Aug 2021 22:35:02

Date of Birth (MMM yyyy)	(b) (6) 2002
Age	18
Age Units	YEARS
Age (Derived)	18
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	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 10 Apr 2021 00:15:34

Generated On: 11 Aug 2021 22:35:02

Date of Informed Consent (<i>dd MMM yyyy</i>)	08 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input 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) 10 Apr 2021 00:15:34

Generated On: 11 Aug 2021 22:35:02

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 10 Apr 2021 00:15:34

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Were any significant conditions reported?

Yes ☐

No ☒

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 10 Apr 2021 00:15:34

Generated On: 11 Aug 2021 22:35:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	08 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	08:45 (24 HR)
Vital Signs Date and Time (derived)	08 AUG 2020 08:45
Height (<i>xxx.x</i>)	179 cm
Weight (<i>xxx.x</i>)	75.1 kg
BMI (<i>xxx.x</i>)	23.43872 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) 10 Apr 2021 00:15:34

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 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) 10 Apr 2021 00:15:34

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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) 10 Apr 2021 00:15:34

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 03:30:29

Generated On: 11 Aug 2021 22:35:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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) 20 Feb 2021 03:30:29

Generated On: 11 Aug 2021 22:35:02

What was the date of randomization? (dd MMM yyyy) 08 AUG 2020

What was the participant's randomization number? 102242

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 20 Feb 2021 03:30:29

Generated On: 11 Aug 2021 22:35:02

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) 20 Feb 2021 03:30:29

Generated On: 11 Aug 2021 22:35:02

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)	08 AUG 2020
Time of assessment (00:00-23:59)	08:45 (24 HR)
Vital Signs Date and Time (derived)	08 AUG 2020 08:45
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 03:30:29

Generated On: 11 Aug 2021 22:35:02

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)	8 AUG 2020
Time of assessment (00:00-23:59)	10:10 (24 HR)
Vital Signs Date and Time (derived)	8 AUG 2020 10:10
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 03:30:29

Generated On: 11 Aug 2021 22:35:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 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) 20 Feb 2021 03:30:29

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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) 08 AUG 2020

What was the treatment time? (00:00-23:59) 09:30 (24 HR)

Treatment Date and Time (derived) 08 AUG 2020 09:30

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) 20 Feb 2021 03:30:29

Generated On: 11 Aug 2021 22:35:02

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

08 AUG 2020

Collection time (00:00-23:59)

08:56 (24 HR)

Collection date and time (derived)

08 AUG 2020 08:56

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 03:30:29

Generated On: 11 Aug 2021 22:35:02

Collection date (dd MMM yyyy)			08 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:54	08 AUG 2020 08:54
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:30:29

Generated On: 11 Aug 2021 22:35:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 10:04

PC Open Date & Time

08 AUG 2020 09:50

PC Close Date & Time

08 AUG 2020 12:20

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.0 °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	08 AUG 2020 19:08
PC Open Date & Time	08 AUG 2020 13:15
PC Close Date & Time	09 AUG 2020 11:59

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:02

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 17:11

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:02

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

97.2 °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

10 AUG 2020 18:37

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

11 AUG 2020 18:02

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:02

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

97.4 °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

12 AUG 2020 19:58

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

13 AUG 2020 18:10

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:02

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

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

14 AUG 2020 18:48

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

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

08 AUG 2020 10:06

PC Open Date & Time

08 AUG 2020 09:50

PC Close Date & Time

08 AUG 2020 12:20

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

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

08 AUG 2020 19:08

PC Open Date & Time

08 AUG 2020 13:15

PC Close Date & Time

09 AUG 2020 11:59

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:02

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

09 AUG 2020 17:11

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:02

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

10 AUG 2020 18:38

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:02

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

11 AUG 2020 18:00

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:02

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

12 AUG 2020 19:58

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:02

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

13 AUG 2020 18:10

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:02

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

14 AUG 2020 18:48

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

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 ☐

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

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

No ☒

Yes ☐

PC Time stamp	08 AUG 2020 10:06
PC Open Date & Time	08 AUG 2020 09:50
PC Close Date & Time	08 AUG 2020 12:20

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

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 ☐

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

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

No ☒

Yes ☐

PC Time stamp	08 AUG 2020 19:09
PC Open Date & Time	08 AUG 2020 13:15
PC Close Date & Time	09 AUG 2020 11:59

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:02

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 17:11
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:02

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 18:38
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:02

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 ☒

PRODUCTION RELEASE (v12.003

45 of 2260

EAB) (1725)

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:02

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 18:01
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:02

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:02

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 19:58
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

49 of 2260

EAB) (1725)

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:02

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 18:10
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:02

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 ☒

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:02

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 18:48
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3362083

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 03:30:28

Generated On: 11 Aug 2021 22:35:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362083

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:30:28

Generated On: 11 Aug 2021 22:35:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362083

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 03:30:22

Generated On: 11 Aug 2021 22:35:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362083

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:30:21

Generated On: 11 Aug 2021 22:35:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362083

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 03:30:22

Generated On: 11 Aug 2021 22:35:02

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

US3362083

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:30:22

Generated On: 11 Aug 2021 22:35:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362083

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 03:30:29

Generated On: 11 Aug 2021 22:35:02

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

US3362083

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:30:29

Generated On: 11 Aug 2021 22:35:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362083

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 03:30:22

Generated On: 11 Aug 2021 22:35:02

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

IN CONVALESCENT

If Contact Not Made, please provide Comments

US3362083

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:30:22

Generated On: 11 Aug 2021 22:35:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362083

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 03:30:28

Generated On: 11 Aug 2021 22:35:02

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

IN CONVALESCENT

If Contact Not Made, please provide Comments

US3362083

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:30:23

Generated On: 11 Aug 2021 22:35:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362083

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 03:30:28

Generated On: 11 Aug 2021 22:35:02

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

IN CONVALESCENT

If Contact Not Made, please provide Comments

US3362083

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:30:28

Generated On: 11 Aug 2021 22:35:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362083

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 03:30:30

Generated On: 11 Aug 2021 22:35:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 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

US3362083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 03:30:30

Generated On: 11 Aug 2021 22:35:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 OCT 2020
Time of assessment (00:00-23:59)	14:09 (24 HR)
Vital Signs Date and Time (derived)	05 OCT 2020 14:09
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3362083

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 03:30:30

Generated On: 11 Aug 2021 22:35:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 OCT 2020

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

US3362083

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 03:30:30

Generated On: 11 Aug 2021 22:35:02

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

05 OCT 2020

Collection time (00:00-23:59)

14:10 (24 HR)

Collection date and time (derived)

05 OCT 2020 14:10

US3362083

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:30:30

Generated On: 11 Aug 2021 22:35:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 OCT 2020 11:07:08
Patient Cloud Open Date & Time	08 OCT 2020 00:01
Patient Cloud Close Date & Time	12 OCT 2020 23:59

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 OCT 2020 02:32:40

Patient Cloud Open Date & Time

15 OCT 2020 00:01

Patient Cloud Close Date & Time

19 OCT 2020 23:59

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 OCT 2020 11:18:33
Patient Cloud Open Date & Time	22 OCT 2020 00:01
Patient Cloud Close Date & Time	26 OCT 2020 23:59

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 NOV 2020 09:34:30
Patient Cloud Open Date & Time	05 NOV 2020 00:01
Patient Cloud Close Date & Time	09 NOV 2020 23:59

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 NOV 2020 12:10:32
Patient Cloud Open Date & Time	12 NOV 2020 00:01
Patient Cloud Close Date & Time	16 NOV 2020 23:59

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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

19 NOV 2020 10:17:38

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

27 NOV 2020 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

30 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

04 DEC 2020 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

[Patient Cloud Close Date & Time](#)

11 DEC 2020 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 DEC 2020 10:29:28
Patient Cloud Open Date & Time	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 DEC 2020 14:04:47

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 00:03:16

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 07:05:41

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 JAN 2021 07:58:03
Patient Cloud Open Date & Time	11 JAN 2021 00:01
Patient Cloud Close Date & Time	15 JAN 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 JAN 2021 12:53:20
Patient Cloud Open Date & Time	18 JAN 2021 00:01
Patient Cloud Close Date & Time	22 JAN 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 JAN 2021 00:06:53

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 FEB 2021 08:27:12
Patient Cloud Open Date & Time	01 FEB 2021 00:01
Patient Cloud Close Date & Time	05 FEB 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 FEB 2021 00:04:41
Patient Cloud Open Date & Time	08 FEB 2021 00:01
Patient Cloud Close Date & Time	12 FEB 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 FEB 2021 00:11:24
Patient Cloud Open Date & Time	15 FEB 2021 00:01
Patient Cloud Close Date & Time	19 FEB 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 FEB 2021 04:29:00
Patient Cloud Open Date & Time	22 FEB 2021 00:01
Patient Cloud Close Date & Time	26 FEB 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 06:03:02

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

08 MAR 2021 00:07:51

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 MAR 2021 00:02:23
Patient Cloud Open Date & Time	15 MAR 2021 00:01
Patient Cloud Close Date & Time	19 MAR 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

Date and time of submission

22 MAR 2021 06:17:49

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 00:15:32

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 06:32:12

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 08:02:29

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 06:10:14

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 07:02:37

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

03 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 <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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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="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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

24 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 ☐

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

[Patient Cloud Open Date & Time](#)

28 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

05 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 ☐

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 <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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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°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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 <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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

23 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 ☐

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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="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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 <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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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°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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	04 OCT 2021 00:01
Patient Cloud Close Date & Time	08 OCT 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 <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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	11 OCT 2021 00:01
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Patient Cloud Close Date & Time	15 OCT 2021 23:59
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US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	18 OCT 2021 00:01
Patient Cloud Close Date & Time	22 OCT 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
Patient Cloud Close Date & Time	29 OCT 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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="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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 NOV 2021 00:01
Patient Cloud Close Date & Time	19 NOV 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

29 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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="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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
Patient Cloud Close Date & Time	17 DEC 2021 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	24 DEC 2021 23:59
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US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 <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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	31 DEC 2021 23:59
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US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 <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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 ☐

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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°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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 <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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 ☐

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 ☐

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 <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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 ☐

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 <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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 ☐

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

21 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

04 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 APR 2022 00:01
Patient Cloud Close Date & Time	29 APR 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 ☐

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 <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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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="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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

23 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 ☐

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

30 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 ☐

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	04 JUL 2022 00:01
Patient Cloud Close Date & Time	08 JUL 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	11 JUL 2022 00:01
Patient Cloud Close Date & Time	15 JUL 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2022 00:01
Patient Cloud Close Date & Time	29 JUL 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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 <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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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°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 ☐

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

03 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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"/>

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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

Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2022 00:01
Patient Cloud Close Date & Time	14 OCT 2022 23:59

US3362083

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:35:02

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 06:03:14

US3362083

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 04:18:27

Generated On: 11 Aug 2021 22:35:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362083

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 04:18:27

Generated On: 11 Aug 2021 22:35:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362083

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362083

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362083

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362083

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362083

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362083

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362083

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3362083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 MAR 2021
Time of assessment (00:00-23:59)	07:42 (24 HR)
Vital Signs Date and Time (derived)	3 MAR 2021 07:42
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3362083

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

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.

US3362083

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 MAR 2021
Collection time (00:00-23:59)	07:45 (24 HR)
Collection date and time (derived)	3 MAR 2021 07:45

US3362083

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362083

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362083

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362083

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

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

US3362083

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 24 Apr 2021 00:10:12

Generated On: 11 Aug 2021 22:35:02

Date of Contact	28 SEP 2020
Time of Contact	13:10
Date and Time of Contact (derived)	28 SEP 2020 13:10
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>

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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 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 checked="" type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	36.8 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	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"/>

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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 28 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 24 Apr 2021 00:10:12

Generated On: 11 Aug 2021 22:35:02

Date of Visit	28 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 type="radio"/> No <input checked="" type="radio"/>
Date of Test	28 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)	0

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) 24 Apr 2021 00:10:12

Generated On: 11 Aug 2021 22:35:02

Date of Contact	31 AUG 2020
Time of Contact	09:30
Date and Time of Contact (derived)	31 AUG 2020 09:30
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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"/>

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	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	97 %	
O2 Saturation Units	%	
Temperature	37 C	
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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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

Symptom Day

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

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	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	97 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 31 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	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 31 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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 31 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

Symptom Day

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

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	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	98 %	
O2 Saturation Units	%	
Temperature	96.5 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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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	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 31 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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 31 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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 31 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	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	97 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 31 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	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 31 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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 ☐

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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 31 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	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	97 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 00:10:13

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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 31 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

Symptom Day

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

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Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	05 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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 31 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	06 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.5 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	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) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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 (8)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

Symptom Day

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

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Form: Symptom Log (8)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	07 SEP 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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

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Form: Symptom Log (8)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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

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Form: Symptom Log (9)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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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Form: Symptom Log (9)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	08 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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 (9)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	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 (9)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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 31 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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 31 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	09 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97 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)

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Generated On: 11 Aug 2021 22:35:02

	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 31 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 24 Apr 2021 00:10:13

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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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Form: Symptom Log (11)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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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Form: Symptom Log (11)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	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	97 %	
O2 Saturation Units	%	
Temperature	97.0 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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	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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Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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 (12)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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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Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	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	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.6 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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Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	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 31 Aug 2020

Form: Symptom Log (12)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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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Form: Symptom Log (13)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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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Form: Symptom Log (13)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	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	98 %	
O2 Saturation Units	%	
Temperature	97.6 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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Generated On: 11 Aug 2021 22:35:02

	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 (13)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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 31 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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 31 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	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	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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 type="checkbox"/>
Day 18	<input checked="" 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 31 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	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	97.6 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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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	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 31 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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 31 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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 31 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	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	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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 31 Aug 2020

Form: Symptom Log (17)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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"/>

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (17)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	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	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (17)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (17)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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 31 Aug 2020

Form: Symptom Log (19)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

Symptom Day

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

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (19)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 AUG 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	99 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 31 Aug 2020

Form: Symptom Log (19)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (19)

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 31 Aug 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 24 Apr 2021 00:10:12

Generated On: 11 Aug 2021 22:35:02

Date of Visit	31 AUG 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	31 AUG 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 24 Apr 2021 00:10:12

Generated On: 11 Aug 2021 22:35:02

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 _____

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 24 Apr 2021 00:10:12

Generated On: 11 Aug 2021 22:35:02

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

Ventilator Support:

High-Flow Oxygen?

Yes ☐

No ☒

Start Date

End Date

Non-Invasive Ventilation?

Yes ☐

No ☒

Start Date

End Date

Mechanical Ventilation?

Yes ☐

No ☒

Start Date

End Date

ECMO?

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 24 Apr 2021 00:10:12

Generated On: 11 Aug 2021 22:35:02

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

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 24 Apr 2021 00:10:12

Generated On: 11 Aug 2021 22:35:02

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3362083

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	2 SEP 2020
Day 5	Yes	4 SEP 2020
Day 7	Yes	6 SEP 2020
Day 9	Yes	8 SEP 2020
Day 14	Yes	13 SEP 2020
Day 21	Yes	20 SEP 2020
Day 28	No	

US3362083

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:09:39

Generated On: 11 Aug 2021 22:35:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3362083

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 00:09:39

Generated On: 11 Aug 2021 22:35:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	11:34 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 11:34
Temperature (xxx.x)	37 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3362083

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 00:09:39

Generated On: 11 Aug 2021 22:35:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

US3362083

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 24 Apr 2021 00:09:39

Generated On: 11 Aug 2021 22:35:02

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

31 AUG 2020

US3362083

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:10:12

Generated On: 11 Aug 2021 22:35:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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	SICKD28

US3362083

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 00:10:12

Generated On: 11 Aug 2021 22:35:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	13:15 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 13:15
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	54 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3362083

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 00:10:12

Generated On: 11 Aug 2021 22:35:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3362083

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 24 Apr 2021 00:10:12

Generated On: 11 Aug 2021 22:35:02

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

28 SEP 2020

US3362083

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

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

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

Visit date (dd MMM yyyy)	06 JAN 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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US3362083

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

Form: Unblinding

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Date of updated informed consent (<i>dd MMM yyyy</i>)	06 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	06 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3362083

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Height	
Weight	
BMI (xxx.x)	

US3362083

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Height	
Weight	
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)	06 JAN 2021
Time of assessment (00:00-23:59)	08:35 (24 HR)
Vital Signs Date and Time (derived)	06 JAN 2021 08:35
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3362083

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Height	
Weight	
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)	06 JAN 2021
Time of assessment (00:00-23:59)	09:26 (24 HR)
Vital Signs Date and Time (derived)	06 JAN 2021 09:26
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3362083

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

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 JAN 2021

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

US3362083

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

Form: Exposure

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

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) 06 JAN 2021

What was the treatment time? (00:00-23:59) 08:51 (24 HR)

Treatment Date and Time (derived) 06 JAN 2021 08:51

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

What was the frequency of the study treatment dosing? ONCE

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

US3362083

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	06 JAN 2021
Collection time (00:00-23:59)	08:13 (24 HR)
Collection date and time (derived)	06 JAN 2021 08:13

US3362083

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	06 JAN 2021
Collection time (00:00 - 23:59)	08:19
Collection Date and Time (derived)	06 JAN 2021 08:19

US3362083

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

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362083

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362083

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

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

US3362083

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 FEB 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

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

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)	5 FEB 2021
Time of assessment (00:00-23:59)	07:44 (24 HR)
Vital Signs Date and Time (derived)	5 FEB 2021 07:44
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

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)	5 FEB 2021
Time of assessment (00:00-23:59)	08:45 (24 HR)
Vital Signs Date and Time (derived)	5 FEB 2021 08:45
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	54 mmHg
Diastolic Blood Pressure units	MMHG

US3362083

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

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.

US3362083

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

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) 5 FEB 2021

What was the treatment time? (00:00-23:59) 08:08 (24 HR)

Treatment Date and Time (derived) 5 FEB 2021 08:08

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

US3362083

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362083

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362083

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362083

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3362083

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 MAR 2021
Time of assessment (00:00-23:59)	07:42 (24 HR)
Vital Signs Date and Time (derived)	3 MAR 2021 07:42
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3362083

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

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.

US3362083

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

3 MAR 2021

Collection time (00:00-23:59)

07:45 (24 HR)

Collection date and time (derived)

3 MAR 2021 07:45

US3362083

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 22:11:36

Generated On: 11 Aug 2021 22:35:02

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3362083

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Mar 2021 22:11:36

Generated On: 11 Aug 2021 22:35:02

AEID	USA-US112-2020-MRNA-1273-P30 1000003
Adverse event	COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	28 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)	06 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 (2)

Data signed: (b) (4) 13 Mar 2021 22:11:36

Generated On: 11 Aug 2021 22:35:02

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	
CONVALESCENT VISIT 31AUG2020 FOR STUDY SWAB COLLECTION THAT WAS CONFIRMED AS POSITIVE ON 04SEP2020. NO REPORT OF EXPOSURE.	
Serious Adverse Event Derived (CSA Programming Field Only)	0

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Mar 2021 22:11:36

Generated On: 11 Aug 2021 22:35:02

Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 00:49:12

Generated On: 11 Aug 2021 22:35:02

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

Yes ☒

No ☐

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

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 00:49:12

Generated On: 11 Aug 2021 22:35:02

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 00:49:12

Generated On: 11 Aug 2021 22:35:02

	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)		31 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 00:49:12

Generated On: 11 Aug 2021 22:35:02

Name of Medication ZINC

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 45

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)

398 of 2260

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 00:49:12

Generated On: 11 Aug 2021 22:35:02

	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)	05 SEP 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"/>

US3362083

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 00:49:12

Generated On: 11 Aug 2021 22:35:02

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3362083

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:35:02

Visit	Screening	<input type="checkbox"/>
	Visit 1 Day 1	<input type="checkbox"/>
	Visit 2 Day 29	<input 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	
Demographics	
Enrollment	
Inclusion/Exclusion Criteria Summary	
Inclusion/Exclusion Criteria	
Medical History Summary	
Medical History	
Vital Signs	
Vital Signs - Dosing	
Physical Examination	
Central Laboratory - Nasopharyngeal Swab	
Childbearing Potential	
Pregnancy Test	
Randomization	
Exposure	
Immunogenicity Assessment	
Saliva Collection	
COVID Diagnostic Test	
Symptom Log	
Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection	
COVID-19 Severity Assessment	
COVID-19 Contact	
Risk of Exposure	
Safety Call	
Dosing Discontinuation	
End of Study / Study Discontinuation	

US3362083

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:35:02

All	
Date of missed or out of window visit or assessment	
Category	
Inclusion criteria not met/Exclusion criteria met	
Study Treatment not given	
Missed Visit	
Missed Assessment	
Visit performed out of window	
Assessment performed out of window	
Scheduled clinical visit performed as home visit	
Other	
Other, specify	
Description of Relationship to COVID-19	
Clinical site closed	
Travel restrictions	
Quarantine due to COVID-19	
Possible exposure to COVID-19	
Exposure to COVID-19	
Presumption / confirmed COVID-19	
Symptoms of COVID-19	
Sponsor hold due to COVID-19	
Participant decision	

US3362083

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

Date of dosing discontinuation (dd MMM yyyy) 31 AUG 2020

Primary reason for dosing discontinuation

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

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

US3362083

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 24 Apr 2021 00:10:13

Generated On: 11 Aug 2021 22:35:02

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 ☐

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

SAEID	USA-US112-2020-MRNA-1273-P301000003
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

SAEID	USA-US112-2020-MRNA-1273-P301000003
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	07/SEP/2020 17:09
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

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

SAEID	USA-US112-2020-MRNA-1273-P301000003
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	09/SEP/2020 20:47
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

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

SAEID	USA-US112-2020-MRNA-1273-P301000003
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	21/SEP/2020 07:43
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

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

SAEID	USA-US112-2020-MRNA-1273-P301000003
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	29/OCT/2020 19:46
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

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

SAEID	USA-US112-2020-MRNA-1273-P301000003
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	05/NOV/2020 08:56
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

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Data signed: (b) (4) 24 Apr 2021 00:09:40

Generated On: 11 Aug 2021 22:35:02

SAEID	USA-US112-2020-MRNA-1273-P301000003
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	20/NOV/2020 10:13
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

US3362083 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

US3362083

Form: Participant Creation

Generated On: 11 Aug 2021 22:35:02

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User entered 'US3362083'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 13:25:53

US3362083

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	08 Aug 2020 14:45:21

US3362083

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered '08 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 13:25:54

US3362083

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered 'Clinic (Clinic)'	Crystal Rowell (b) (4)	08 Aug 2020 14:45:21

US3362083

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User entered 'SCRN'	System	08 Aug 2020 14:45:21

US3362083

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:02

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered (b) (6) 2002'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 13:25:55

US3362083

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:02

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered '18'	Crystal Rowell (b) (4)	08 Aug 2020 14:45:41

US3362083

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:02

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User entered 'YEARS'	System	08 Aug 2020 14:45:41

US3362083

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:02

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User entered '18'	System	08 Aug 2020 14:46:12

US3362083

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:02

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered 'Male (M)'	Crystal Rowell (b) (4)	08 Aug 2020 14:45:41

US3362083

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:02

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Crystal Rowell (b) (4)	08 Aug 2020 14:45:41

US3362083

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:02

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered 'I'	Crystal Rowell (b) (4)	08 Aug 2020 14:45:41

US3362083

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:02

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered '0'	Crystal Rowell (b) (4)	08 Aug 2020 14:45:41

US3362083

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:02

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered '0'	Crystal Rowell (b) (4)	08 Aug 2020 14:45:41

US3362083

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:02

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered '0'	Crystal Rowell (b) (4)	08 Aug 2020 14:45:41

US3362083

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:02

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered '0'	Crystal Rowell (b) (4)	08 Aug 2020 14:45:41

US3362083

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:02

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered '0'	Crystal Rowell (b) (4)	08 Aug 2020 14:45:41

US3362083

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:02

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered empty.	Crystal Rowell (b) (4)	08 Aug 2020 14:45:41

US3362083

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:02

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered '0'	Crystal Rowell (b) (4)	08 Aug 2020 14:45:41

US3362083

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:02

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered '0'	Crystal Rowell (b) (4)	08 Aug 2020 14:45:41

US3362083

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:02

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered '08 Aug 2020'	Crystal Rowell (b) (4)	08 Aug 2020 14:46:12

US3362083

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User entered 'Aug 2020'	System	08 Aug 2020 14:46:12

US3362083

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User entered '2020'	System	08 Aug 2020 14:46:12

US3362083

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:02

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered 'Amendment 1 (1)'	Crystal Rowell (b) (4)	08 Aug 2020 14:46:12

US3362083

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	08 Aug 2020 14:46:12

US3362083

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:02

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered empty.	Crystal Rowell (b) (4)	08 Aug 2020 14:46:12

US3362083

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:02

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered empty.	Crystal Rowell (b) (4)	08 Aug 2020 14:46:12

US3362083

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:02

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered 'No (N)'	Crystal Rowell (b) (4)	08 Aug 2020 14:46:12

US3362083

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:02

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 13:25:54

US3362083

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:02

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User entered 'I'	System	08 Aug 2020 14:46:23

US3362083

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	08 Aug 2020 14:46:23

US3362083

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:35:02

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:41:34

US3362083

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:43:36

US3362083

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered '08 Aug 2020'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:43:36

US3362083

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User closed query 'Per CDM: Please confirm if time 08:45 is AM or PM. Thank you!' (Site from DM).	(b) (4)	25 Sep 2020 08:40:12
Query 'Per CDM: Please confirm if time 08:45 is AM or PM. Thank you!' answered with 'am' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 18:23:00
User opened query 'Per CDM: Please confirm if time 08:45 is AM or PM. Thank you!' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 10:50:29
User entered '08:45' reason for change: Data Entry Error	Amy Thomassie (b) (4)	05 Sep 2020 16:03:21
User entered '08:40'	(b) (4)	08 Aug 2020 15:43:36

US3362083

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User entered '08 Aug 2020 08:45'	System	05 Sep 2020 16:03:21
User entered '08 Aug 2020 08:40'	System	08 Aug 2020 15:43:36

US3362083

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered '179' cm	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:43:36
DataPoint set to visible.	System	08 Aug 2020 14:46:23

US3362083

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered '75.1' kg	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:43:36
DataPoint set to visible.	System	08 Aug 2020 14:46:23

US3362083

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
Amendment Manager: User entered '23.43872'	System	16 Sep 2020 23:48:31
User entered '23.4'	System	08 Aug 2020 15:43:36
DataPoint set to visible.	System	08 Aug 2020 14:46:23

US3362083

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User entered 'kg/m2'	System	08 Aug 2020 15:43:36
DataPoint set to visible.	System	08 Aug 2020 14:46:23

US3362083

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 08:40:13
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 18:23:35
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 18:23:29
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 10:49:43
User entered '36.8' C	(b) (4), (b) (6)	08 Aug 2020 15:43:36

US3362083

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 18:23:29
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Aug 2020 15:43:36

US3362083

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:43:36

US3362083

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 18:23:29
User entered '61'	(b) (4), (b) (6)	08 Aug 2020 15:43:36

US3362083

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User entered 'bpm'	System	08 Aug 2020 15:43:36

US3362083

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 18:23:29
User entered '17'	(b) (4), (b) (6)	08 Aug 2020 15:43:36

US3362083

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User entered 'breaths/min'	System	08 Aug 2020 15:43:36

US3362083

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 18:23:29
User entered '104'	(b) (4), (b) (6)	08 Aug 2020 15:43:36

US3362083

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User entered 'mmHg'	System	08 Aug 2020 15:43:36

US3362083

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 18:23:29
User entered '69'	(b) (4), (b) (6)	08 Aug 2020 15:43:36

US3362083

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User entered 'mmHg'	System	08 Aug 2020 15:43:36

US3362083

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30

US3362083

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:43:50

US3362083

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:02

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered '08 Aug 2020'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:43:50

US3362083

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:46:24

US3362083

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:46:24

US3362083

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:46:24

US3362083

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	(b) (4), (b) (6)	
	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	08 Aug 2020 15:46:24

US3362083

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:46:24

US3362083

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:46:24

US3362083

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:46:24

US3362083

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:46:24

US3362083

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:46:24

US3362083

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:46:24

US3362083

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:46:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:02

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Aug 2020 15:46:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Aug 2020 15:46:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Aug 2020 15:46:36
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Aug 2020 15:46:24
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 15:46:24

US3362083

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:02

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 15:46:24

US3362083

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:02

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 15:46:24

US3362083

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:46:24

US3362083

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 15:46:24

US3362083

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:46:24

US3362083

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:46:24

US3362083

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:46:24

US3362083

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:02

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 15:46:24

US3362083

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:02

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:22:30
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:15:34
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 15:46:24

US3362083

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	08 Aug 2020 14:46:44

US3362083

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '08 Aug 2020'	Crystal Rowell (b) (4)	08 Aug 2020 14:46:44

US3362083

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

[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 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'Clinic (Clinic)'	Crystal Rowell (b) (4)	08 Aug 2020 14:46:44

US3362083

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User entered 'VISIT1'	System	08 Aug 2020 14:46:44

US3362083

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '08 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 14:10:30

US3362083

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:03:34
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:03:34
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Aug 2020 14:10:30
User entered '102242' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 14:10:30

US3362083

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 14:10:30

US3362083

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:02

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 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:47:32

US3362083

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:02

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 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:47:32

US3362083

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:47:32

US3362083

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:02

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:47:32

US3362083

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:02

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'No (N)'	(b) (4), (b) (6)	08 Aug 2020 15:47:32

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 08:40:06
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 18:23:53
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 18:23:48
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 10:50:48
User entered '179' cm	(b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 18:23:48
User entered '75.1' kg	(b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:02

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 08:40:06
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 18:23:53
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 18:23:48
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 10:50:48
User entered '179' cm	(b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 18:23:48
User entered '75.1' kg	(b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '08 Aug 2020'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '08:45'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User entered '08 Aug 2020 08:45'	System	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	29 Aug 2020 19:32:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	29 Aug 2020 19:32:23
User entered '61' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:32:23
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Aug 2020 15:48:52
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User entered 'bpm'	System	29 Aug 2020 19:32:23
User entered empty.	System	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	29 Aug 2020 19:32:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	29 Aug 2020 19:32:23
User entered '17' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:32:23
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Aug 2020 15:48:52
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User entered 'breaths/min'	System	29 Aug 2020 19:32:23
User entered empty.	System	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	29 Aug 2020 19:32:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	29 Aug 2020 19:32:23
User entered '104' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:32:23
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Aug 2020 15:48:52
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User entered 'mmHg'	System	29 Aug 2020 19:32:23
User entered empty.	System	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	29 Aug 2020 19:32:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	29 Aug 2020 19:32:23
User entered '69' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:32:23
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Aug 2020 15:48:52
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User entered 'mmHg'	System	29 Aug 2020 19:32:23
User entered empty.	System	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 08:40:06
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 18:23:53
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 18:23:48
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 10:50:48
User entered '179' cm	(b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 18:23:48
User entered '75.1' kg	(b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Aug 2020 19:33:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 19:33:19
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:33:19
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Aug 2020 15:48:52
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '8 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:33:19
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '10:10' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:33:19
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User entered '8 Aug 2020 10:10'	System	29 Aug 2020 19:33:19
User entered empty.	System	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User closed query 'Per CDM: Data is missing, please update as needed.' (Site from DM).	(b) (4)	31 Aug 2020 17:35:53
Query 'Per CDM: Data is missing, please update as needed.' answered with '?' (Site from DM).	(b) (4), (b) (6)	29 Aug 2020 19:33:47
User entered '36.8' C reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:33:19
User opened query 'Per CDM: Data is missing, please update as needed.' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 15:21:23
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:33:19
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '50' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:33:19
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User entered 'bpm'	System	29 Aug 2020 19:33:19
User entered empty.	System	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:33:19
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User entered 'breaths/min'	System	29 Aug 2020 19:33:19
User entered empty.	System	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '108' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:33:19
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User entered 'mmHg'	System	29 Aug 2020 19:33:19
User entered empty.	System	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '66' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:33:19
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User entered 'mmHg'	System	29 Aug 2020 19:33:19
User entered empty.	System	08 Aug 2020 15:48:52

US3362083

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:49:15

US3362083

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:02

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '08 Aug 2020'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:49:15

US3362083

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	08 Aug 2020 14:47:13

US3362083

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered empty.	Crystal Rowell (b) (4)	08 Aug 2020 14:47:13

US3362083

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

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 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered empty.	Crystal Rowell (b) (4)	08 Aug 2020 14:47:13

US3362083

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User entered 'MRNA-1273 OR PLACEBO'	System	08 Aug 2020 14:47:13

US3362083

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '08 Aug 2020'	Crystal Rowell (b) (4)	08 Aug 2020 14:47:13

US3362083

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '09:30'	Crystal Rowell (b) (4)	08 Aug 2020 14:47:13

US3362083

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User entered '08 Aug 2020 09:30'	System	08 Aug 2020 14:47:13

US3362083

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'Right Arm (RIGHT ARM)'	Crystal Rowell (b) (4)	08 Aug 2020 14:47:13

US3362083

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User entered 'ONCE'	System	08 Aug 2020 14:47:13

US3362083

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User entered 'INTRAMUSCULAR'	System	08 Aug 2020 14:47:13

US3362083

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:50:24

US3362083

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '08 Aug 2020'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:50:24

US3362083

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '08:56'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:50:24

US3362083

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User entered '08 Aug 2020 08:56'	System	08 Aug 2020 15:50:24

US3362083

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:35:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '08 Aug 2020'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:50:52

US3362083

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	08 Aug 2020 15:50:52

US3362083

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:50:52

US3362083

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '08:54'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:50:52

US3362083

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User entered '08 Aug 2020 08:54'	System	08 Aug 2020 15:50:52

US3362083

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	08 Aug 2020 15:50:52

US3362083

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Aug 2020 20:53:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 20:53:45
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	11 Aug 2020 20:53:45
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Aug 2020 15:50:52
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 15:50:52

US3362083

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:50:52

US3362083

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User entered empty.	System	08 Aug 2020 15:50:52

US3362083

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:53:18

US3362083

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User entered 'I'	System	08 Aug 2020 15:53:18

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T10:04:24', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '522f6a61-b174-4d83-b479-96d5f43d3635' User entered 'Yes (Y)'	System	08 Aug 2020 15:04:47
	System	08 Aug 2020 15:04:47

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T10:04:32', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '522f6a61-b174-4d83-b479-96d5f43d3635' User entered '98.4'	System	08 Aug 2020 15:04:47
	System	08 Aug 2020 15:04:47

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T10:04:35', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '522f6a61-b174-4d83-b479-96d5f43d3635' User entered 'No (N)'	System	08 Aug 2020 15:04:47
	System	08 Aug 2020 15:04:47

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T10:04:45', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '522f6a61-b174-4d83-b479-96d5f43d3635' User entered '08 Aug 2020 10:04'	System	08 Aug 2020 15:04:47
	System	08 Aug 2020 15:04:47

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '08 Aug 2020 09:50'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '08 Aug 2020 12:20'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T19:07:52', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '1db7971f-3c5f-4d78-8cd8-413fe796e404'	System	09 Aug 2020 00:08:03
User entered 'Yes (Y)'	System	09 Aug 2020 00:08:03

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T19:07:56', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '1db7971f-3c5f-4d78-8cd8-413fe796e404' User entered '97.0'	System	09 Aug 2020 00:08:03
	System	09 Aug 2020 00:08:03

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T19:07:58', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '1db7971f-3c5f-4d78-8cd8-413fe796e404'	System	09 Aug 2020 00:08:03
User entered 'No (N)'	System	09 Aug 2020 00:08:03

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T19:08:02', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '1db7971f-3c5f-4d78-8cd8-413fe796e404'	System	09 Aug 2020 00:08:03
User entered '08 Aug 2020 19:08'	System	09 Aug 2020 00:08:03

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '08 Aug 2020 13:15'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 2'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-09T17:11:12', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '37c3baa8-8e33-41bd-b950-bbf14727c88e' User entered 'Yes (Y)'	System	09 Aug 2020 22:11:24
	System	09 Aug 2020 22:11:24

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-09T17:11:15', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '37c3baa8-8e33-41bd-b950-bbf14727c88e' User entered '96.8'	System	09 Aug 2020 22:11:24
	System	09 Aug 2020 22:11:24

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-09T17:11:17', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '37c3baa8-8e33-41bd-b950-bbf14727c88e'	System	09 Aug 2020 22:11:24
User entered 'No (N)'	System	09 Aug 2020 22:11:24

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-09T17:11:20', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '37c3baa8-8e33-41bd-b950-bbf14727c88e' User entered '09 Aug 2020 17:11'	System	09 Aug 2020 22:11:24
	System	09 Aug 2020 22:11:24

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 3'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-10T18:37:32', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'c95be980-472b-4dff-b638-36455b15f363' User entered 'Yes (Y)'	System	10 Aug 2020 23:37:49
	System	10 Aug 2020 23:37:49

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-10T18:37:37', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'c95be980-472b-4dff-b638-36455b15f363' User entered '97.2'	System	10 Aug 2020 23:37:49
	System	10 Aug 2020 23:37:49

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-10T18:37:40', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'c95be980-472b-4dff-b638-36455b15f363' User entered 'No (N)'	System	10 Aug 2020 23:37:49
	System	10 Aug 2020 23:37:49

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-10T18:37:48', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'c95be980-472b-4dff-b638-36455b15f363' User entered '10 Aug 2020 18:37'	System	10 Aug 2020 23:37:49
	System	10 Aug 2020 23:37:49

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 4'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-11T18:02:03', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '3744d102-7ee4-4b57-b9df-202407482446'	System	11 Aug 2020 23:02:47
User entered 'Yes (Y)'	System	11 Aug 2020 23:02:47

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-11T18:02:31', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '3744d102-7ee4-4b57-b9df-202407482446' User entered '98.0'	System	11 Aug 2020 23:02:47
	System	11 Aug 2020 23:02:47

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-11T18:02:37', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '3744d102-7ee4-4b57-b9df-202407482446'	System	11 Aug 2020 23:02:47
User entered 'No (N)'	System	11 Aug 2020 23:02:47

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-11T18:02:43', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '3744d102-7ee4-4b57-b9df-202407482446'	System	11 Aug 2020 23:02:47
User entered '11 Aug 2020 18:02'	System	11 Aug 2020 23:02:47

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 5'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-12T19:58:20', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'f9ba9b52-0e6c-4cb0-84d5-f4d3cb28bd94'	System	13 Aug 2020 00:58:34
User entered 'Yes (Y)'	System	13 Aug 2020 00:58:34

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-12T19:58:26', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'f9ba9b52-0e6c-4cb0-84d5-f4d3cb28bd94' User entered '97.4'	System	13 Aug 2020 00:58:34
	System	13 Aug 2020 00:58:34

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-12T19:58:28', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'f9ba9b52-0e6c-4cb0-84d5-f4d3cb28bd94'	System	13 Aug 2020 00:58:34
User entered 'No (N)'	System	13 Aug 2020 00:58:34

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-12T19:58:31', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'f9ba9b52-0e6c-4cb0-84d5-f4d3cb28bd94'	System	13 Aug 2020 00:58:34
User entered '12 Aug 2020 19:58'	System	13 Aug 2020 00:58:34

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 6'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-13T18:10:20', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '0b0d6cea-27c0-47c0-a3ed-0596e15c1c4d' User entered 'Yes (Y)'	System	13 Aug 2020 23:10:30
	System	13 Aug 2020 23:10:30

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-13T18:10:23', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '0b0d6cea-27c0-47c0-a3ed-0596e15c1c4d' User entered '97.8'	System	13 Aug 2020 23:10:30
	System	13 Aug 2020 23:10:30

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-13T18:10:25', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '0b0d6cea-27c0-47c0-a3ed-0596e15c1c4d' User entered 'No (N)'	System	13 Aug 2020 23:10:30
	System	13 Aug 2020 23:10:30

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-13T18:10:26', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '0b0d6cea-27c0-47c0-a3ed-0596e15c1c4d' User entered '13 Aug 2020 18:10'	System	13 Aug 2020 23:10:30
	System	13 Aug 2020 23:10:30

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 7'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-14T18:48:34', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '18f0c523-9729-4ebf-b549-00c1c3dd7660' User entered 'Yes (Y)'	System	14 Aug 2020 23:48:44
	System	14 Aug 2020 23:48:44

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-14T18:48:36', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '18f0c523-9729-4ebf-b549-00c1c3dd7660' User entered '98.0'	System	14 Aug 2020 23:48:44
	System	14 Aug 2020 23:48:44

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-14T18:48:38', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '18f0c523-9729-4ebf-b549-00c1c3dd7660'	System	14 Aug 2020 23:48:44
User entered 'No (N)'	System	14 Aug 2020 23:48:44

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-14T18:48:40', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '18f0c523-9729-4ebf-b549-00c1c3dd7660'	System	14 Aug 2020 23:48:44
User entered '14 Aug 2020 18:48'	System	14 Aug 2020 23:48:44

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T10:05:51', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '791331c2-4565-4cca-af57-bf60f9df222b' User entered 'None (1)'	System	08 Aug 2020 15:06:06
	System	08 Aug 2020 15:06:06

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T10:05:53', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '791331c2-4565-4cca-af57-bf60f9df222b' User entered 'No (N)'	System	08 Aug 2020 15:06:06
	System	08 Aug 2020 15:06:06

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T10:05:55', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '791331c2-4565-4cca-af57-bf60f9df222b' User entered 'No (N)'	System	08 Aug 2020 15:06:06
	System	08 Aug 2020 15:06:06

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T10:06:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '791331c2-4565-4cca-af57-bf60f9df222b' User entered 'None (1)'	System	08 Aug 2020 15:06:06
	System	08 Aug 2020 15:06:06

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T10:06:02', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '791331c2-4565-4cca-af57-bf60f9df222b'	System	08 Aug 2020 15:06:06
User entered '08 Aug 2020 10:06'	System	08 Aug 2020 15:06:06

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '08 Aug 2020 09:50'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '08 Aug 2020 12:20'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T19:08:06', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'c2c69394-e74b-455c-a54f-0a604ad4fe85'	System	09 Aug 2020 00:08:19
User entered 'None (1)'	System	09 Aug 2020 00:08:19

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T19:08:08', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'c2c69394-e74b-455c-a54f-0a604ad4fe85'	System	09 Aug 2020 00:08:19
User entered 'No (N)'	System	09 Aug 2020 00:08:19

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T19:08:11', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'c2c69394-e74b-455c-a54f-0a604ad4fe85'	System	09 Aug 2020 00:08:19
User entered 'No (N)'	System	09 Aug 2020 00:08:19

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T19:08:13', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'c2c69394-e74b-455c-a54f-0a604ad4fe85'	System	09 Aug 2020 00:08:19
User entered 'None (1)'	System	09 Aug 2020 00:08:19

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T19:08:18', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'c2c69394-e74b-455c-a54f-0a604ad4fe85'	System	09 Aug 2020 00:08:19
User entered '08 Aug 2020 19:08'	System	09 Aug 2020 00:08:19

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '08 Aug 2020 13:15'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 2'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-09T17:11:23', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'dec8ae17-c455-4b6d-b35c-7c8286f8cc4a' User entered 'None (1)'	System	09 Aug 2020 22:11:35
	System	09 Aug 2020 22:11:35

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-09T17:11:25', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'dec8ae17-c455-4b6d-b35c-7c8286f8cc4a'	System	09 Aug 2020 22:11:35
User entered 'No (N)'	System	09 Aug 2020 22:11:35

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-09T17:11:26', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'dec8ae17-c455-4b6d-b35c-7c8286f8cc4a' User entered 'No (N)'	System	09 Aug 2020 22:11:35
	System	09 Aug 2020 22:11:35

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-09T17:11:30', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'dec8ae17-c455-4b6d-b35c-7c8286f8cc4a' User entered 'None (1)'	System	09 Aug 2020 22:11:35
	System	09 Aug 2020 22:11:35

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-09T17:11:32', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'dec8ae17-c455-4b6d-b35c-7c8286f8cc4a' User entered '09 Aug 2020 17:11'	System	09 Aug 2020 22:11:35
	System	09 Aug 2020 22:11:35

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 3'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-10T18:37:52', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'ffe36447-ca67-4c1b-83ab-686f5f4acd7b'	System	10 Aug 2020 23:38:01
User entered 'None (1)'	System	10 Aug 2020 23:38:01

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-10T18:37:53', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'ffe36447-ca67-4c1b-83ab-686f5f4acd7b'	System	10 Aug 2020 23:38:01
User entered 'No (N)'	System	10 Aug 2020 23:38:01

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-10T18:37:55', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'ffe36447-ca67-4c1b-83ab-686f5f4acd7b'	System	10 Aug 2020 23:38:01
User entered 'No (N)'	System	10 Aug 2020 23:38:01

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-10T18:37:57', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'ffe36447-ca67-4c1b-83ab-686f5f4acd7b'	System	10 Aug 2020 23:38:01
User entered 'None (1)'	System	10 Aug 2020 23:38:01

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-10T18:38:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'ffe36447-ca67-4c1b-83ab-686f5f4acd7b' User entered '10 Aug 2020 18:38'	System	10 Aug 2020 23:38:01
	System	10 Aug 2020 23:38:01

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 4'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-11T18:00:41', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'd7a80895-458b-40cb-ae76-473325f3809d' User entered 'None (1)'	System	11 Aug 2020 23:00:52
	System	11 Aug 2020 23:00:52

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-11T18:00:43', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'd7a80895-458b-40cb-ae76-473325f3809d' User entered 'No (N)'	System	11 Aug 2020 23:00:52
	System	11 Aug 2020 23:00:52

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-11T18:00:46', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'd7a80895-458b-40cb-ae76-473325f3809d' User entered 'No (N)'	System	11 Aug 2020 23:00:52
	System	11 Aug 2020 23:00:52

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-11T18:00:47', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'd7a80895-458b-40cb-ae76-473325f3809d' User entered 'None (1)'	System	11 Aug 2020 23:00:52
	System	11 Aug 2020 23:00:52

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-11T18:00:49', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'd7a80895-458b-40cb-ae76-473325f3809d' User entered '11 Aug 2020 18:00'	System	11 Aug 2020 23:00:52
	System	11 Aug 2020 23:00:52

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 5'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-12T19:58:34', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '5f8cf50f-a54a-4559-bdd3-6a5ecaf35915'	System	13 Aug 2020 00:58:43
User entered 'None (1)'	System	13 Aug 2020 00:58:43

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-12T19:58:35', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '5f8cf50f-a54a-4559-bdd3-6a5ecaf35915' User entered 'No (N)'	System	13 Aug 2020 00:58:43
	System	13 Aug 2020 00:58:43

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-12T19:58:36', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '5f8cf50f-a54a-4559-bdd3-6a5ecaf35915' User entered 'No (N)'	System	13 Aug 2020 00:58:43
	System	13 Aug 2020 00:58:43

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-12T19:58:37', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '5f8cf50f-a54a-4559-bdd3-6a5ecaf35915'	System	13 Aug 2020 00:58:43
User entered 'None (1)'	System	13 Aug 2020 00:58:43

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-12T19:58:40', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '5f8cf50f-a54a-4559-bdd3-6a5ecaf35915'	System	13 Aug 2020 00:58:43
User entered '12 Aug 2020 19:58'	System	13 Aug 2020 00:58:43

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 6'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-13T18:10:29', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '89020d14-094d-409e-9242-c661165c2ede' User entered 'None (1)'	System	13 Aug 2020 23:10:36
	System	13 Aug 2020 23:10:36

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-13T18:10:30', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '89020d14-094d-409e-9242-c661165c2ede' User entered 'No (N)'	System	13 Aug 2020 23:10:36
	System	13 Aug 2020 23:10:36

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-13T18:10:32', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '89020d14-094d-409e-9242-c661165c2ede' User entered 'No (N)'	System	13 Aug 2020 23:10:36
	System	13 Aug 2020 23:10:36

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-13T18:10:34', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '89020d14-094d-409e-9242-c661165c2ede' User entered 'None (1)'	System	13 Aug 2020 23:10:36
	System	13 Aug 2020 23:10:36

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-13T18:10:35', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '89020d14-094d-409e-9242-c661165c2ede' User entered '13 Aug 2020 18:10'	System	13 Aug 2020 23:10:36
	System	13 Aug 2020 23:10:36

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 7'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-14T18:48:43', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '0807624f-8003-4ca4-89b4-274e2c155e67'	System	14 Aug 2020 23:48:51
User entered 'None (1)'	System	14 Aug 2020 23:48:51

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-14T18:48:44', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '0807624f-8003-4ca4-89b4-274e2c155e67' User entered 'No (N)'	System	14 Aug 2020 23:48:51
	System	14 Aug 2020 23:48:51

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-14T18:48:45', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '0807624f-8003-4ca4-89b4-274e2c155e67' User entered 'No (N)'	System	14 Aug 2020 23:48:51
	System	14 Aug 2020 23:48:51

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-14T18:48:46', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '0807624f-8003-4ca4-89b4-274e2c155e67'	System	14 Aug 2020 23:48:51
User entered 'None (1)'	System	14 Aug 2020 23:48:51

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-14T18:48:48', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '0807624f-8003-4ca4-89b4-274e2c155e67' User entered '14 Aug 2020 18:48'	System	14 Aug 2020 23:48:51
	System	14 Aug 2020 23:48:51

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T10:06:06', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '98c9026b-1d71-4f8b-b9d3-5807dfdef30c' User entered 'None (0)'	System	08 Aug 2020 15:06:36
	System	08 Aug 2020 15:06:36

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T10:06:08', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '98c9026b-1d71-4f8b-b9d3-5807dfdef30c' User entered 'None (0)'	System	08 Aug 2020 15:06:36
	System	08 Aug 2020 15:06:36

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T10:06:09', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '98c9026b-1d71-4f8b-b9d3-5807dfdef30c' User entered 'None (0)'	System	08 Aug 2020 15:06:36
	System	08 Aug 2020 15:06:36

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T10:06:12', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '98c9026b-1d71-4f8b-b9d3-5807dfdef30c' User entered 'None (0)'	System	08 Aug 2020 15:06:36
	System	08 Aug 2020 15:06:36

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T10:06:16', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '98c9026b-1d71-4f8b-b9d3-5807dfdef30c' User entered 'None (0)'	System	08 Aug 2020 15:06:36
	System	08 Aug 2020 15:06:36

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T10:06:23', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '98c9026b-1d71-4f8b-b9d3-5807dfdef30c' User entered 'None (0)'	System	08 Aug 2020 15:06:36
	System	08 Aug 2020 15:06:36

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

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)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T10:06:28', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '98c9026b-1d71-4f8b-b9d3-5807dfdef30c' User entered 'No (N)'	System	08 Aug 2020 15:06:36
	System	08 Aug 2020 15:06:36

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T10:06:34', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '98c9026b-1d71-4f8b-b9d3-5807dfdef30c'	System	08 Aug 2020 15:06:36
User entered '08 Aug 2020 10:06'	System	08 Aug 2020 15:06:36

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '08 Aug 2020 09:50'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '08 Aug 2020 12:20'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T19:08:32', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '69deac43-2d3c-4463-b9ae-d478a8bcd30f'	System	09 Aug 2020 00:09:06
User entered 'No interference with activity (1)'	System	09 Aug 2020 00:09:06

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T19:08:34', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '69deac43-2d3c-4463-b9ae-d478a8bcd30f' User entered 'None (0)'	System	09 Aug 2020 00:09:06
	System	09 Aug 2020 00:09:06

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T19:08:35', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '69deac43-2d3c-4463-b9ae-d478a8bcd30f' User entered 'None (0)'	System	09 Aug 2020 00:09:06
	System	09 Aug 2020 00:09:06

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T19:08:37', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '69deac43-2d3c-4463-b9ae-d478a8bcd30f' User entered 'None (0)'	System	09 Aug 2020 00:09:06
	System	09 Aug 2020 00:09:06

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T19:08:38', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '69deac43-2d3c-4463-b9ae-d478a8bcd30f' User entered 'None (0)'	System	09 Aug 2020 00:09:06
	System	09 Aug 2020 00:09:06

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T19:08:41', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '69deac43-2d3c-4463-b9ae-d478a8bcd30f' User entered 'None (0)'	System	09 Aug 2020 00:09:06
	System	09 Aug 2020 00:09:06

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

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)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T19:08:45', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '69deac43-2d3c-4463-b9ae-d478a8bcd30f' User entered 'No (N)'	System	09 Aug 2020 00:09:06
	System	09 Aug 2020 00:09:06

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-08T19:09:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '69deac43-2d3c-4463-b9ae-d478a8bcd30f' User entered '08 Aug 2020 19:09'	System	09 Aug 2020 00:09:06
	System	09 Aug 2020 00:09:06

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '08 Aug 2020 13:15'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 2'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-09T17:11:36', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '19f9cc0f-891d-46a4-8a83-276949719b42'	System	09 Aug 2020 22:11:51
User entered 'None (0)'	System	09 Aug 2020 22:11:51

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-09T17:11:37', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '19f9cc0f-891d-46a4-8a83-276949719b42'	System	09 Aug 2020 22:11:51
User entered 'None (0)'	System	09 Aug 2020 22:11:51

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-09T17:11:38', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '19f9cc0f-891d-46a4-8a83-276949719b42' User entered 'None (0)'	System	09 Aug 2020 22:11:51
	System	09 Aug 2020 22:11:51

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-09T17:11:40', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '19f9cc0f-891d-46a4-8a83-276949719b42' User entered 'None (0)'	System	09 Aug 2020 22:11:51
	System	09 Aug 2020 22:11:51

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-09T17:11:41', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '19f9cc0f-891d-46a4-8a83-276949719b42' User entered 'None (0)'	System	09 Aug 2020 22:11:51
	System	09 Aug 2020 22:11:51

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-09T17:11:42', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '19f9cc0f-891d-46a4-8a83-276949719b42'	System	09 Aug 2020 22:11:51
User entered 'None (0)'	System	09 Aug 2020 22:11:51

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:02

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)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-09T17:11:45', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '19f9cc0f-891d-46a4-8a83-276949719b42'	System	09 Aug 2020 22:11:51
User entered 'No (N)'	System	09 Aug 2020 22:11:51

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-09T17:11:47', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '19f9cc0f-891d-46a4-8a83-276949719b42'	System	09 Aug 2020 22:11:51
User entered '09 Aug 2020 17:11'	System	09 Aug 2020 22:11:51

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 3'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-10T18:38:42', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '57cc2a64-32ee-4514-8df8-d1eb8641da17'	System	10 Aug 2020 23:38:55
User entered 'No interference with activity (1)'	System	10 Aug 2020 23:38:55

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-10T18:38:43', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '57cc2a64-32ee-4514-8df8-d1eb8641da17' User entered 'None (0)'	System	10 Aug 2020 23:38:55
	System	10 Aug 2020 23:38:55

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-10T18:38:44', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '57cc2a64-32ee-4514-8df8-d1eb8641da17' User entered 'None (0)'	System	10 Aug 2020 23:38:55
	System	10 Aug 2020 23:38:55

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-10T18:38:45', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '57cc2a64-32ee-4514-8df8-d1eb8641da17' User entered 'None (0)'	System	10 Aug 2020 23:38:55
	System	10 Aug 2020 23:38:55

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-10T18:38:47', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '57cc2a64-32ee-4514-8df8-d1eb8641da17' User entered 'None (0)'	System	10 Aug 2020 23:38:55
	System	10 Aug 2020 23:38:55

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-10T18:38:48', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '57cc2a64-32ee-4514-8df8-d1eb8641da17' User entered 'None (0)'	System	10 Aug 2020 23:38:55
	System	10 Aug 2020 23:38:55

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:02

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)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-10T18:38:49', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '57cc2a64-32ee-4514-8df8-d1eb8641da17' User entered 'No (N)'	System	10 Aug 2020 23:38:55
	System	10 Aug 2020 23:38:55

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-10T18:38:54', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '57cc2a64-32ee-4514-8df8-d1eb8641da17' User entered '10 Aug 2020 18:38'	System	10 Aug 2020 23:38:55
	System	10 Aug 2020 23:38:55

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 4'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-11T18:00:52', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'd8b1fe24-752c-4bf3-8217-4537d89eca96'	System	11 Aug 2020 23:01:11
User entered 'None (0)'	System	11 Aug 2020 23:01:11

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-11T18:00:54', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'd8b1fe24-752c-4bf3-8217-4537d89eca96'	System	11 Aug 2020 23:01:11
User entered 'None (0)'	System	11 Aug 2020 23:01:11

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-11T18:00:55', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'd8b1fe24-752c-4bf3-8217-4537d89eca96' User entered 'None (0)'	System	11 Aug 2020 23:01:11
	System	11 Aug 2020 23:01:11

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-11T18:00:56', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'd8b1fe24-752c-4bf3-8217-4537d89eca96' User entered 'None (0)'	System	11 Aug 2020 23:01:11
	System	11 Aug 2020 23:01:11

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-11T18:00:57', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'd8b1fe24-752c-4bf3-8217-4537d89eca96'	System	11 Aug 2020 23:01:11
User entered 'None (0)'	System	11 Aug 2020 23:01:11

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-11T18:00:59', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'd8b1fe24-752c-4bf3-8217-4537d89eca96' User entered 'None (0)'	System	11 Aug 2020 23:01:11
	System	11 Aug 2020 23:01:11

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:02

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)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-11T18:01:01', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'd8b1fe24-752c-4bf3-8217-4537d89eca96'	System	11 Aug 2020 23:01:11
User entered 'No (N)'	System	11 Aug 2020 23:01:11

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-11T18:01:06', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'd8b1fe24-752c-4bf3-8217-4537d89eca96'	System	11 Aug 2020 23:01:11
User entered '11 Aug 2020 18:01'	System	11 Aug 2020 23:01:11

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 5'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-12T19:58:42', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '1aa5b8c0-a211-44ab-aec3-f073733b9832' User entered 'None (0)'	System	13 Aug 2020 00:58:53
	System	13 Aug 2020 00:58:53

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-12T19:58:43', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '1aa5b8c0-a211-44ab-aec3-f073733b9832' User entered 'None (0)'	System	13 Aug 2020 00:58:53
	System	13 Aug 2020 00:58:53

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-12T19:58:44', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '1aa5b8c0-a211-44ab-aec3-f073733b9832' User entered 'None (0)'	System	13 Aug 2020 00:58:53
	System	13 Aug 2020 00:58:53

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-12T19:58:45', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '1aa5b8c0-a211-44ab-aec3-f073733b9832' User entered 'None (0)'	System	13 Aug 2020 00:58:53
	System	13 Aug 2020 00:58:53

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-12T19:58:47', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '1aa5b8c0-a211-44ab-aec3-f073733b9832' User entered 'None (0)'	System	13 Aug 2020 00:58:53
	System	13 Aug 2020 00:58:53

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-12T19:58:48', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '1aa5b8c0-a211-44ab-aec3-f073733b9832' User entered 'None (0)'	System	13 Aug 2020 00:58:53
	System	13 Aug 2020 00:58:53

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:02

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)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-12T19:58:50', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '1aa5b8c0-a211-44ab-aec3-f073733b9832' User entered 'No (N)'	System	13 Aug 2020 00:58:53
	System	13 Aug 2020 00:58:53

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-12T19:58:51', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '1aa5b8c0-a211-44ab-aec3-f073733b9832'	System	13 Aug 2020 00:58:53
User entered '12 Aug 2020 19:58'	System	13 Aug 2020 00:58:53

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 6'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-13T18:10:38', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '2d06d9c4-b7c0-4681-bffa-d88cf68e3b5f' User entered 'None (0)'	System	13 Aug 2020 23:10:49
	System	13 Aug 2020 23:10:49

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-13T18:10:39', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '2d06d9c4-b7c0-4681-bffa-d88cf68e3b5f' User entered 'None (0)'	System	13 Aug 2020 23:10:49
	System	13 Aug 2020 23:10:49

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-13T18:10:40', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '2d06d9c4-b7c0-4681-bffa-d88cf68e3b5f' User entered 'None (0)'	System	13 Aug 2020 23:10:49
	System	13 Aug 2020 23:10:49

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-13T18:10:41', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '2d06d9c4-b7c0-4681-bffa-d88cf68e3b5f' User entered 'None (0)'	System	13 Aug 2020 23:10:49
	System	13 Aug 2020 23:10:49

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-13T18:10:42', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '2d06d9c4-b7c0-4681-bffa-d88cf68e3b5f' User entered 'None (0)'	System	13 Aug 2020 23:10:49
	System	13 Aug 2020 23:10:49

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-13T18:10:43', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '2d06d9c4-b7c0-4681-bffa-d88cf68e3b5f' User entered 'None (0)'	System	13 Aug 2020 23:10:49
	System	13 Aug 2020 23:10:49

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:02

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)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-13T18:10:45', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '2d06d9c4-b7c0-4681-bffa-d88cf68e3b5f' User entered 'No (N)'	System	13 Aug 2020 23:10:49
	System	13 Aug 2020 23:10:49

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-13T18:10:46', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '2d06d9c4-b7c0-4681-bffa-d88cf68e3b5f' User entered '13 Aug 2020 18:10'	System	13 Aug 2020 23:10:49
	System	13 Aug 2020 23:10:49

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 7'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-14T18:48:50', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '8a28f7a0-9ca2-499d-ba09-343a899b6be6' User entered 'None (0)'	System	14 Aug 2020 23:49:04
	System	14 Aug 2020 23:49:04

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-14T18:48:51', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '8a28f7a0-9ca2-499d-ba09-343a899b6be6' User entered 'None (0)'	System	14 Aug 2020 23:49:04
	System	14 Aug 2020 23:49:04

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-14T18:48:52', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '8a28f7a0-9ca2-499d-ba09-343a899b6be6' User entered 'None (0)'	System	14 Aug 2020 23:49:04
	System	14 Aug 2020 23:49:04

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-14T18:48:53', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '8a28f7a0-9ca2-499d-ba09-343a899b6be6' User entered 'None (0)'	System	14 Aug 2020 23:49:04
	System	14 Aug 2020 23:49:04

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-14T18:48:55', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '8a28f7a0-9ca2-499d-ba09-343a899b6be6' User entered 'None (0)'	System	14 Aug 2020 23:49:04
	System	14 Aug 2020 23:49:04

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-14T18:48:56', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '8a28f7a0-9ca2-499d-ba09-343a899b6be6' User entered 'None (0)'	System	14 Aug 2020 23:49:04
	System	14 Aug 2020 23:49:04

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:02

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)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-14T18:48:57', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '8a28f7a0-9ca2-499d-ba09-343a899b6be6'	System	14 Aug 2020 23:49:04
User entered 'No (N)'	System	14 Aug 2020 23:49:04

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-08-14T18:48:58', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '8a28f7a0-9ca2-499d-ba09-343a899b6be6' User entered '14 Aug 2020 18:48'	System	14 Aug 2020 23:49:04
	System	14 Aug 2020 23:49:04

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 14:47:13

US3362083

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 14:47:13

US3362083

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	31 Aug 2020 13:52:41

US3362083

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '15 Aug 2020'	Crystal Rowell (b) (4)	31 Aug 2020 13:52:41

US3362083

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'Contact Made (CONTACT MADE)'	Crystal Rowell (b) (4)	31 Aug 2020 13:52:41

US3362083

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered empty.	Crystal Rowell (b) (4)	31 Aug 2020 13:52:41

US3362083

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	31 Aug 2020 13:52:47

US3362083

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User entered 'I'	System	31 Aug 2020 13:52:47

US3362083

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:23
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	31 Aug 2020 13:53:43

US3362083

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:23
User entered '24 Aug 2020'	Crystal Rowell (b) (4)	31 Aug 2020 13:53:43

US3362083

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:23
User entered 'Contact Made (CONTACT MADE)'	Crystal Rowell (b) (4)	31 Aug 2020 13:53:43

US3362083

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:23
User entered empty.	Crystal Rowell (b) (4)	31 Aug 2020 13:53:43

US3362083

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:23
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	31 Aug 2020 13:53:49

US3362083

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:39:05
User entered '1'	System	31 Aug 2020 13:53:49

US3362083

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:23
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	31 Aug 2020 14:49:13

US3362083

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:23
User entered '31 Aug 2020'	Crystal Rowell (b) (4)	31 Aug 2020 14:49:13

US3362083

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:23
User entered 'Contact Made (CONTACT MADE)'	Crystal Rowell (b) (4)	31 Aug 2020 14:49:13

US3362083

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:23
User entered empty.	Crystal Rowell (b) (4)	31 Aug 2020 14:49:13

US3362083

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:23
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	31 Aug 2020 14:49:19

US3362083

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User entered 'I'	System	31 Aug 2020 14:49:19

US3362083

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'No (N)'	Crystal Rowell (b) (4)	30 Sep 2020 15:58:35

US3362083

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 15:58:35

US3362083

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered empty.	Crystal Rowell (b) (4)	30 Sep 2020 15:58:35

US3362083

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User entered 'VISIT2'	System	30 Sep 2020 15:58:35

US3362083

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	30 Sep 2020 15:58:40

US3362083

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User entered '1'	System	30 Sep 2020 15:58:40

US3362083

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:27:28

US3362083

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:23
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:27:28

US3362083

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:23
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:27:28

US3362083

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:23
User entered 'In convalescent'	(b) (4), (b) (6)	06 Oct 2020 15:27:28

US3362083

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:27:33

US3362083

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User entered 'I'	System	06 Oct 2020 15:27:33

US3362083

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:27:42

US3362083

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:27:42

US3362083

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:27:42

US3362083

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'In convalescent'	(b) (4), (b) (6)	06 Oct 2020 15:27:42

US3362083

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:27:45

US3362083

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User entered 'I'	System	06 Oct 2020 15:27:45

US3362083

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:27:55

US3362083

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:27:55

US3362083

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:27:55

US3362083

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'In convalescent'	(b) (4), (b) (6)	06 Oct 2020 15:27:55

US3362083

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:28:01

US3362083

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User entered 'I'	System	06 Oct 2020 15:28:01

US3362083

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:29:34

US3362083

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '05 Oct 2020' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 18:39:33
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	(b) (4), (b) (6)	06 Nov 2020 18:39:33
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	02 Nov 2020 20:42:26
User entered '5 Oct 2020'	System	02 Nov 2020 20:40:54
	(b) (4), (b) (6)	06 Oct 2020 15:29:34

US3362083

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:29:34

US3362083

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User entered 'VISIT3'	System	06 Oct 2020 15:29:34

US3362083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:30:16

US3362083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User closed query 'Per CDM: Please consider updating the Date format to DD-MMM-YYYY including 2 digits for the day (for example 01-JAN-1999). ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 01:59:32
Query 'Per CDM: Please consider updating the Date format to DD-MMM-YYYY including 2 digits for the day (for example 01-JAN-1999). ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 18:39:20
User entered '05 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 18:39:09
User opened query 'Per CDM: Please consider updating the Date format to DD-MMM-YYYY including 2 digits for the day (for example 01-JAN-1999). ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 18:13:26
User closed query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	02 Nov 2020 20:42:26
User opened query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	02 Nov 2020 20:40:54
User entered '5 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 15:30:16

US3362083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '14:09'	(b) (4), (b) (6)	06 Oct 2020 15:30:16

US3362083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User entered '05 Oct 2020 14:09'	System	06 Nov 2020 18:39:09
User entered '5 Oct 2020 14:09'	System	06 Oct 2020 15:30:16

US3362083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:30:16

US3362083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:30:16

US3362083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:30:16

US3362083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '80'	(b) (4), (b) (6)	06 Oct 2020 15:30:16

US3362083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User entered 'bpm'	System	06 Oct 2020 15:30:16

US3362083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '18'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:30:16

US3362083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User entered 'breaths/min'	System	06 Oct 2020 15:30:16

US3362083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '107'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:30:16

US3362083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User entered 'mmHg'	System	06 Oct 2020 15:30:16

US3362083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '64'	(b) (4), (b) (6)	06 Oct 2020 15:30:16

US3362083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User entered 'mmHg'	System	06 Oct 2020 15:30:16

US3362083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45

US3362083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45

US3362083

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:30:21

US3362083

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '05 Oct 2020' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 18:39:41
User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 20:42:26
User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).		02 Nov 2020 20:40:54
User entered '5 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 15:30:21

US3362083

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 15:30:41

US3362083

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '05 Oct 2020' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 18:39:48
User closed query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	02 Nov 2020 20:42:26
User opened query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	02 Nov 2020 20:40:54
User entered '5 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 15:30:41

US3362083

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered '14:10'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:30:41

US3362083

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User entered '05 Oct 2020 14:10'	System	06 Nov 2020 18:39:48
User entered '5 Oct 2020 14:10'	System	06 Oct 2020 15:30:41

US3362083

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:30:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:30:46

US3362083

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User entered '1'	System	06 Oct 2020 15:30:46

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 64'	System	08 Aug 2020 14:47:13

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-10-08T11:07:02', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '587f30f4-1ae1-40f5-ac7a-47bd4ac9a118'	System	08 Oct 2020 16:07:12
User entered 'No (N)'	System	08 Oct 2020 16:07:12

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Have you been exposed to someone with 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)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-10-08T11:07:05', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '587f30f4-1ae1-40f5-ac7a-47bd4ac9a118'	System	08 Oct 2020 16:07:12
User entered 'No (N)'	System	08 Oct 2020 16:07:12

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-10-08T11:07:08', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '587f30f4-1ae1-40f5-ac7a-47bd4ac9a118' User entered '08 Oct 2020 11:07:08'	System	08 Oct 2020 16:07:12
	System	08 Oct 2020 16:07:12

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered '08 Oct 2020 00:01'	System	08 Aug 2020 14:47:13

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered '12 Oct 2020 23:59'	System	08 Aug 2020 14:47:13

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 71'	System	08 Aug 2020 14:47:13

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[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)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-10-16T02:32:37', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'ab1caa29-fe21-4a86-b883-60c67e933e82'	System	16 Oct 2020 07:32:43
User entered 'No (N)'	System	16 Oct 2020 07:32:43

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Have you been exposed to someone with 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)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-10-16T02:32:38', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'ab1caa29-fe21-4a86-b883-60c67e933e82'	System	16 Oct 2020 07:32:43
User entered 'No (N)'	System	16 Oct 2020 07:32:43

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-10-16T02:32:40', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'ab1caa29-fe21-4a86-b883-60c67e933e82' User entered '16 Oct 2020 02:32:40'	System	16 Oct 2020 07:32:43
	System	16 Oct 2020 07:32:43

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered '15 Oct 2020 00:01'	System	08 Aug 2020 14:47:13

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered '19 Oct 2020 23:59'	System	08 Aug 2020 14:47:13

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 78'	System	08 Aug 2020 14:47:13

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[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)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-10-22T11:18:28', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'd46d264a-66b8-4c0c-a2ae-08e8438e113e'	System	22 Oct 2020 16:18:36
User entered 'No (N)'	System	22 Oct 2020 16:18:36

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Have you been exposed to someone with 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)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-10-22T11:18:30', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'd46d264a-66b8-4c0c-a2ae-08e8438e113e'	System	22 Oct 2020 16:18:36
User entered 'No (N)'	System	22 Oct 2020 16:18:36

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-10-22T11:18:33', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'd46d264a-66b8-4c0c-a2ae-08e8438e113e' User entered '22 Oct 2020 11:18:33'	System	22 Oct 2020 16:18:36
	System	22 Oct 2020 16:18:36

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered '22 Oct 2020 00:01'	System	08 Aug 2020 14:47:13

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
Data entry locked.	System	08 Aug 2020 14:47:13
User entered '26 Oct 2020 23:59'	System	08 Aug 2020 14:47:13

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
DataPoint Activated.	System	02 Nov 2020 20:42:26
DataPoint Inactivated.	System	02 Nov 2020 20:40:54
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 92'	System	08 Aug 2020 14:47:13

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[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)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-11-05T09:34:25', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '1f9689a2-975b-49d9-babc-98f5e42e5f43'	System	05 Nov 2020 15:34:33
User entered 'No (N)'	System	05 Nov 2020 15:34:33
DataPoint Activated.	System	02 Nov 2020 20:42:26
DataPoint Inactivated.	System	02 Nov 2020 20:40:54

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Have you been exposed to someone with 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)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-11-05T09:34:28', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '1f9689a2-975b-49d9-babc-98f5e42e5f43'	System	05 Nov 2020 15:34:33
User entered 'No (N)'	System	05 Nov 2020 15:34:33
DataPoint Activated.	System	02 Nov 2020 20:42:26
DataPoint Inactivated.	System	02 Nov 2020 20:40:54

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-11-05T09:34:30', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '1f9689a2-975b-49d9-babc-98f5e42e5f43'	System	05 Nov 2020 15:34:33
User entered '05 Nov 2020 09:34:30'	System	05 Nov 2020 15:34:33
DataPoint Activated.	System	02 Nov 2020 20:42:26
DataPoint Inactivated.	System	02 Nov 2020 20:40:54

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
DataPoint Activated.	System	02 Nov 2020 20:42:26
DataPoint Inactivated.	System	02 Nov 2020 20:40:54
Data entry locked.	System	08 Aug 2020 14:47:13
User entered '05 Nov 2020 00:01'	System	08 Aug 2020 14:47:13

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
DataPoint Activated.	System	02 Nov 2020 20:42:26
DataPoint Inactivated.	System	02 Nov 2020 20:40:54
Data entry locked.	System	08 Aug 2020 14:47:13
User entered '09 Nov 2020 23:59'	System	08 Aug 2020 14:47:13

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
DataPoint Activated.	System	02 Nov 2020 20:42:26
DataPoint Inactivated.	System	02 Nov 2020 20:40:54
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 99'	System	08 Aug 2020 14:47:13

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[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)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-11-14T12:10:28', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'dd0be8c9-c299-4b1d-b75a-17a8dea73934'	System	14 Nov 2020 18:10:35
User entered 'No (N)'	System	14 Nov 2020 18:10:35
DataPoint Activated.	System	02 Nov 2020 20:42:26
DataPoint Inactivated.	System	02 Nov 2020 20:40:54

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Have you been exposed to someone with 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)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-11-14T12:10:30', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'dd0be8c9-c299-4b1d-b75a-17a8dea73934'	System	14 Nov 2020 18:10:35
User entered 'No (N)'	System	14 Nov 2020 18:10:35
DataPoint Activated.	System	02 Nov 2020 20:42:26
DataPoint Inactivated.	System	02 Nov 2020 20:40:54

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-11-14T12:10:32', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'dd0be8c9-c299-4b1d-b75a-17a8dea73934'	System	14 Nov 2020 18:10:35
User entered '14 Nov 2020 12:10:32'	System	14 Nov 2020 18:10:35
DataPoint Activated.	System	02 Nov 2020 20:42:26
DataPoint Inactivated.	System	02 Nov 2020 20:40:54

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
DataPoint Activated.	System	02 Nov 2020 20:42:26
DataPoint Inactivated.	System	02 Nov 2020 20:40:54
Data entry locked.	System	08 Aug 2020 14:47:13
User entered '12 Nov 2020 00:01'	System	08 Aug 2020 14:47:13

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
DataPoint Activated.	System	02 Nov 2020 20:42:26
DataPoint Inactivated.	System	02 Nov 2020 20:40:54
Data entry locked.	System	08 Aug 2020 14:47:13
User entered '16 Nov 2020 23:59'	System	08 Aug 2020 14:47:13

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
DataPoint Activated.	System	02 Nov 2020 20:42:26
DataPoint Inactivated.	System	02 Nov 2020 20:40:54
Data entry locked.	System	08 Aug 2020 14:47:13
User entered 'Day 106'	System	08 Aug 2020 14:47:13

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

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)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-11-19T10:17:35', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '1f1118df-761d-46a6-b7d5-1aa56357502d'	System	19 Nov 2020 16:17:44
User entered 'No (N)'	System	19 Nov 2020 16:17:44
DataPoint Activated.	System	02 Nov 2020 20:42:26
DataPoint Inactivated.	System	02 Nov 2020 20:40:54

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Have you been exposed to someone with 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)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-11-19T10:17:36', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '1f1118df-761d-46a6-b7d5-1aa56357502d'	System	19 Nov 2020 16:17:44
User entered 'No (N)'	System	19 Nov 2020 16:17:44
DataPoint Activated.	System	02 Nov 2020 20:42:26
DataPoint Inactivated.	System	02 Nov 2020 20:40:54

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5D0B53BE-7B3F-494A-A82D-D5FF2A885249)', Time: '2020-11-19T10:17:38', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '1f1118df-761d-46a6-b7d5-1aa56357502d' User entered '19 Nov 2020 10:17:38'	System	19 Nov 2020 16:17:44
DataPoint Activated.	System	02 Nov 2020 20:42:26
DataPoint Inactivated.	System	02 Nov 2020 20:40:54

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
DataPoint Activated.	System	02 Nov 2020 20:42:26
DataPoint Inactivated.	System	02 Nov 2020 20:40:54
Data entry locked.	System	08 Aug 2020 14:47:13
User entered '19 Nov 2020 00:01'	System	08 Aug 2020 14:47:13

US3362083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:23:39
DataPoint Activated.	System	02 Nov 2020 20:42:26
DataPoint Inactivated.	System	02 Nov 2020 20:40:54
Data entry locked.	System	08 Aug 2020 14:47:13
User entered '23 Nov 2020 23:59'	System	08 Aug 2020 14:47:13

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2020-12-18T10:29:23', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'd5ea041a-e40a-4105-94b5-47151257922f' User entered 'No (N)'	System	18 Dec 2020 16:29:30
	System	18 Dec 2020 16:29:30

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Have you been exposed to someone with 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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2020-12-18T10:29:25', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'd5ea041a-e40a-4105-94b5-47151257922f' User entered 'No (N)'	System	18 Dec 2020 16:29:30
	System	18 Dec 2020 16:29:30

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2020-12-18T10:29:28', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'd5ea041a-e40a-4105-94b5-47151257922f' User entered '18 Dec 2020 10:29:28'	System	18 Dec 2020 16:29:30
	System	18 Dec 2020 16:29:30

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2020-12-21T14:04:44', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '22ccc56b-7dbb-451e-807d-5816a9ece9b2' User entered 'No (N)'	System	21 Dec 2020 21:04:49
	System	21 Dec 2020 21:04:49

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Have you been exposed to someone with 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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2020-12-21T14:04:45', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '22ccc56b-7dbb-451e-807d-5816a9ece9b2' User entered 'No (N)'	System	21 Dec 2020 21:04:49
	System	21 Dec 2020 21:04:49

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2020-12-21T14:04:47', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '22ccc56b-7dbb-451e-807d-5816a9ece9b2' User entered '21 Dec 2020 14:04:47'	System	21 Dec 2020 21:04:49
	System	21 Dec 2020 21:04:49

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2020-12-28T00:03:12', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '3d9009c5-1375-43ed-8e6a-509170165c9c' User entered 'No (N)'	System	28 Dec 2020 06:03:21
	System	28 Dec 2020 06:03:21

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Have you been exposed to someone with 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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2020-12-28T00:03:14', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '3d9009c5-1375-43ed-8e6a-509170165c9c' User entered 'No (N)'	System	28 Dec 2020 06:03:21
	System	28 Dec 2020 06:03:21

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2020-12-28T00:03:16', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '3d9009c5-1375-43ed-8e6a-509170165c9c' User entered '28 Dec 2020 00:03:16'	System	28 Dec 2020 06:03:21
	System	28 Dec 2020 06:03:21

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-01-04T07:05:37', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'f11a2380-1356-45cb-9fba-7df960d2c152'	System	04 Jan 2021 13:05:43
User entered 'No (N)'	System	04 Jan 2021 13:05:43

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Have you been exposed to someone with 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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-01-04T07:05:39', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'f11a2380-1356-45cb-9fba-7df960d2c152'	System	04 Jan 2021 13:05:43
User entered 'No (N)'	System	04 Jan 2021 13:05:43

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-01-04T07:05:41', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'f11a2380-1356-45cb-9fba-7df960d2c152' User entered '04 Jan 2021 07:05:41'	System	04 Jan 2021 13:05:43
	System	04 Jan 2021 13:05:43

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-01-11T07:57:58', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'fc3d4fce-9c04-40ad-8233-064f630ac875' User entered 'No (N)'	System	11 Jan 2021 13:58:06
	System	11 Jan 2021 13:58:06

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Have you been exposed to someone with 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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-01-11T07:58:01', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'fc3d4fce-9c04-40ad-8233-064f630ac875'	System	11 Jan 2021 13:58:06
User entered 'No (N)'	System	11 Jan 2021 13:58:06

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-01-11T07:58:03', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'fc3d4fce-9c04-40ad-8233-064f630ac875' User entered '11 Jan 2021 07:58:03'	System	11 Jan 2021 13:58:06
	System	11 Jan 2021 13:58:06

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-01-18T12:53:17', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'b1d09004-11d7-4238-85bf-2949c9ace30a' User entered 'No (N)'	System	18 Jan 2021 18:53:23
	System	18 Jan 2021 18:53:23

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Have you been exposed to someone with 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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-01-18T12:53:18', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'b1d09004-11d7-4238-85bf-2949c9ace30a' User entered 'No (N)'	System	18 Jan 2021 18:53:23
	System	18 Jan 2021 18:53:23

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-01-18T12:53:20', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'b1d09004-11d7-4238-85bf-2949c9ace30a' User entered '18 Jan 2021 12:53:20'	System	18 Jan 2021 18:53:23
	System	18 Jan 2021 18:53:23

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-01-25T00:06:50', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '7e2d0f2a-a5ef-4ca5-a597-c15e76fa3633' User entered 'No (N)'	System	25 Jan 2021 06:06:55
	System	25 Jan 2021 06:06:55

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Have you been exposed to someone with 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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-01-25T00:06:51', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '7e2d0f2a-a5ef-4ca5-a597-c15e76fa3633' User entered 'No (N)'	System	25 Jan 2021 06:06:55
	System	25 Jan 2021 06:06:55

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-01-25T00:06:53', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '7e2d0f2a-a5ef-4ca5-a597-c15e76fa3633' User entered '25 Jan 2021 00:06:53'	System	25 Jan 2021 06:06:55
	System	25 Jan 2021 06:06:55

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-02-01T08:27:09', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '1bd3bdae-9904-48d5-b302-51e720a5a73c' User entered 'No (N)'	System	01 Feb 2021 14:27:14
	System	01 Feb 2021 14:27:14

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Have you been exposed to someone with 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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-02-01T08:27:10', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '1bd3bdae-9904-48d5-b302-51e720a5a73c'	System	01 Feb 2021 14:27:14
User entered 'No (N)'	System	01 Feb 2021 14:27:14

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-02-01T08:27:12', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '1bd3bdae-9904-48d5-b302-51e720a5a73c' User entered '01 Feb 2021 08:27:12'	System	01 Feb 2021 14:27:14
	System	01 Feb 2021 14:27:14

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-02-08T00:04:37', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '1f3c589f-b3fa-46e0-ac75-7e50a4e8fd1e' User entered 'No (N)'	System	08 Feb 2021 06:04:45

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Have you been exposed to someone with 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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-02-08T00:04:38', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '1f3c589f-b3fa-46e0-ac75-7e50a4e8fd1e' User entered 'No (N)'	System	08 Feb 2021 06:04:45

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-02-08T00:04:41', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '1f3c589f-b3fa-46e0-ac75-7e50a4e8fd1e' User entered '08 Feb 2021 00:04:41'	System	08 Feb 2021 06:04:45
	System	08 Feb 2021 06:04:45

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-02-15T00:11:21', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '2c5fd466-aa89-4d8c-86a7-e83476bd9d4a' User entered 'No (N)'	System	15 Feb 2021 06:11:26
	System	15 Feb 2021 06:11:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Have you been exposed to someone with 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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-02-15T00:11:22', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '2c5fd466-aa89-4d8c-86a7-e83476bd9d4a' User entered 'No (N)'	System	15 Feb 2021 06:11:26
	System	15 Feb 2021 06:11:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-02-15T00:11:24', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '2c5fd466-aa89-4d8c-86a7-e83476bd9d4a' User entered '15 Feb 2021 00:11:24'	System	15 Feb 2021 06:11:26
	System	15 Feb 2021 06:11:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-02-22T04:28:55', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'c07852e0-02cb-4e12-a938-75b4b992571f' User entered 'No (N)'	System	22 Feb 2021 10:29:03
	System	22 Feb 2021 10:29:03

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Have you been exposed to someone with 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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-02-22T04:28:58', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'c07852e0-02cb-4e12-a938-75b4b992571f' User entered 'No (N)'	System	22 Feb 2021 10:29:03

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-02-22T04:29:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'c07852e0-02cb-4e12-a938-75b4b992571f' User entered '22 Feb 2021 04:29:00'	System	22 Feb 2021 10:29:03
	System	22 Feb 2021 10:29:03

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-03-01T00:02:59-06:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'b52b2357-06f6-4ef4-b1ef-607052314e63'	System	01 Mar 2021 06:03:08
User entered 'No (N)'	System	01 Mar 2021 06:03:08

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Have you been exposed to someone with 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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-03-01T00:03:01-06:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'b52b2357-06f6-4ef4-b1ef-607052314e63'	System	01 Mar 2021 06:03:08
User entered 'No (N)'	System	01 Mar 2021 06:03:08

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-03-01T00:03:02-06:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'b52b2357-06f6-4ef4-b1ef-607052314e63'	System	01 Mar 2021 06:03:08
User entered '01 Mar 2021 06:03:02'	System	01 Mar 2021 06:03:08

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-03-08T00:07:43-06:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '7acaacf2-98fe-461c-b268-33bd7700d9d3'	System	08 Mar 2021 06:07:53
User entered 'No (N)'	System	08 Mar 2021 06:07:53

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Have you been exposed to someone with 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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-03-08T00:07:45-06:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '7acaacf2-98fe-461c-b268-33bd7700d9d3'	System	08 Mar 2021 06:07:53
User entered 'No (N)'	System	08 Mar 2021 06:07:53

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-03-08T00:07:51-06:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '7acaacf2-98fe-461c-b268-33bd7700d9d3' User entered '08 Mar 2021 00:07:51'	System	08 Mar 2021 06:07:53
	System	08 Mar 2021 06:07:53

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-03-15T00:02:18-05:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '97221f39-650e-4ab6-ae9a-f5a22d7a9292'	System	15 Mar 2021 05:02:28
User entered 'No (N)'	System	15 Mar 2021 05:02:28

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Have you been exposed to someone with 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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-03-15T00:02:19-05:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '97221f39-650e-4ab6-ae9a-f5a22d7a9292'	System	15 Mar 2021 05:02:28
User entered 'No (N)'	System	15 Mar 2021 05:02:28

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-03-15T00:02:23-05:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '97221f39-650e-4ab6-ae9a-f5a22d7a9292' User entered '15 Mar 2021 00:02:23'	System	15 Mar 2021 05:02:28
	System	15 Mar 2021 05:02:28

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-03-22T06:17:44-05:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'ebe3c4e5-e42e-4b24-b174-5052fb421c15'	System	22 Mar 2021 11:17:52
User entered 'No (N)'	System	22 Mar 2021 11:17:52

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Have you been exposed to someone with 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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-03-22T06:17:46-05:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'ebe3c4e5-e42e-4b24-b174-5052fb421c15'	System	22 Mar 2021 11:17:52
User entered 'No (N)'	System	22 Mar 2021 11:17:52

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-03-22T06:17:49-05:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'ebe3c4e5-e42e-4b24-b174-5052fb421c15'	System	22 Mar 2021 11:17:52
User entered '22 Mar 2021 06:17:49'	System	22 Mar 2021 11:17:52

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-03-29T00:15:27-05:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'a5e6c3dd-fce8-49e0-85dc-594d1c9dc638'	System	29 Mar 2021 05:15:39
User entered 'No (N)'	System	29 Mar 2021 05:15:39

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Have you been exposed to someone with 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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-03-29T00:15:28-05:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'a5e6c3dd-fce8-49e0-85dc-594d1c9dc638'	System	29 Mar 2021 05:15:39
User entered 'No (N)'	System	29 Mar 2021 05:15:39

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-03-29T00:15:32-05:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'a5e6c3dd-fce8-49e0-85dc-594d1c9dc638' User entered '29 Mar 2021 00:15:32'	System	29 Mar 2021 05:15:39
	System	29 Mar 2021 05:15:39

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-04-05T06:32:09-05:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '92ae60a4-348a-488c-9b0b-7cad83aaf6d0'	System	05 Apr 2021 11:32:17
User entered 'No (N)'	System	05 Apr 2021 11:32:17

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Have you been exposed to someone with 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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-04-05T06:32:10-05:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '92ae60a4-348a-488c-9b0b-7cad83aaf6d0'	System	05 Apr 2021 11:32:17
User entered 'No (N)'	System	05 Apr 2021 11:32:17

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-04-05T06:32:12-05:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '92ae60a4-348a-488c-9b0b-7cad83aaf6d0'	System	05 Apr 2021 11:32:17
User entered '05 Apr 2021 06:32:12'	System	05 Apr 2021 11:32:17

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-04-12T08:02:25-05:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'e5021474-1b9c-41d4-ad3b-22e44a7bda53'	System	12 Apr 2021 13:02:31
User entered 'No (N)'	System	12 Apr 2021 13:02:31

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Have you been exposed to someone with 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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-04-12T08:02:27-05:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'e5021474-1b9c-41d4-ad3b-22e44a7bda53'	System	12 Apr 2021 13:02:31
User entered 'No (N)'	System	12 Apr 2021 13:02:31

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-04-12T08:02:29-05:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'e5021474-1b9c-41d4-ad3b-22e44a7bda53'	System	12 Apr 2021 13:02:31
User entered '12 Apr 2021 08:02:29'	System	12 Apr 2021 13:02:31

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-04-19T06:10:11-05:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'b5804c56-f0b3-4c75-8c31-3ce1712229f0'	System	19 Apr 2021 11:10:17
User entered 'No (N)'	System	19 Apr 2021 11:10:17

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Have you been exposed to someone with 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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-04-19T06:10:12-05:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'b5804c56-f0b3-4c75-8c31-3ce1712229f0'	System	19 Apr 2021 11:10:17
User entered 'No (N)'	System	19 Apr 2021 11:10:17

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-04-19T06:10:14-05:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: 'b5804c56-f0b3-4c75-8c31-3ce1712229f0'	System	19 Apr 2021 11:10:17
User entered '19 Apr 2021 06:10:14'	System	19 Apr 2021 11:10:17

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-04-26T07:02:34-05:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '0b13f377-8a30-402c-a73e-58934f5691d5' User entered 'No (N)'	System	26 Apr 2021 12:02:39
	System	26 Apr 2021 12:02:39

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

Have you been exposed to someone with 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 (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-04-26T07:02:35-05:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '0b13f377-8a30-402c-a73e-58934f5691d5'	System	26 Apr 2021 12:02:39
User entered 'No (N)'	System	26 Apr 2021 12:02:39

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-04-26T07:02:37-05:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '0b13f377-8a30-402c-a73e-58934f5691d5'	System	26 Apr 2021 12:02:39
User entered '26 Apr 2021 07:02:37'	System	26 Apr 2021 12:02:39

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '10 Oct 2022 00:01'	System	19 Nov 2020 16:28:26

US3362083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:26
Amendment Manager: User entered '14 Oct 2022 23:59'	System	19 Nov 2020 16:28:26

US3362083

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:35:02

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)	26 Apr 2021 06:19:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-03-01T00:03:09-06:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '2ceadcac-9b7f-4a26-992e-b07daf5dd4d4'	System	01 Mar 2021 06:03:17
User entered 'No (N)'	System	01 Mar 2021 06:03:17

US3362083

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:35:02

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:19:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F738A027-2128-47F3-987D-22B5CA894DEC)', Time: '2021-03-01T00:03:14-06:00', User OID: 'PatientReportedOutcome (US3362083)', ODM File OID: '2ceadcac-9b7f-4a26-992e-b07daf5dd4d4' User entered '01 Mar 2021 06:03:14'	System	01 Mar 2021 06:03:17
	System	01 Mar 2021 06:03:17

US3362083

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:18:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 16:44:50

US3362083

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:18:27
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	02 Nov 2020 20:42:26
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	02 Nov 2020 20:40:54
User entered '28 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 16:44:50

US3362083

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:18:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:44:50

US3362083

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:18:27
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 16:44:50

US3362083

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:18:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 16:44:55

US3362083

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:13:45
User entered 'I'	System	28 Oct 2020 16:44:55

US3362083

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Dec 2020 15:54:07

US3362083

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '01 Dec 2020'	(b) (4), (b) (6)	01 Dec 2020 15:54:07

US3362083

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:54:07

US3362083

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered empty.	(b) (4), (b) (6)	01 Dec 2020 15:54:07

US3362083

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	14 Dec 2020 16:35:26

US3362083

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:41
User entered 'I'	System	14 Dec 2020 16:35:26

US3362083

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 15:22:30

US3362083

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '31 Dec 2020'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 15:22:30

US3362083

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 15:22:30

US3362083

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 15:22:30

US3362083

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 15:26:13

US3362083

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:41
User entered 'I'	System	31 Dec 2020 15:26:13

US3362083

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	03 Mar 2021 14:33:42

US3362083

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '1 Feb 2021' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	03 Mar 2021 14:34:08
User entered '3 Mar 2021'	Alexandra Caillouet (b) (4)	03 Mar 2021 14:33:42

US3362083

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Contact Made (CONTACT MADE)'	Alexandra Caillouet (b) (4)	03 Mar 2021 14:33:42

US3362083

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered empty.	Alexandra Caillouet (b) (4)	03 Mar 2021 14:33:42

US3362083

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	03 Mar 2021 14:33:47

US3362083

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:41
User entered 'I'	System	03 Mar 2021 14:33:47

US3362083

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	03 Mar 2021 14:34:18

US3362083

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '3 Mar 2021'	Alexandra Caillouet (b) (4)	03 Mar 2021 14:34:18

US3362083

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

[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 18:16:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Clinic (Clinic)'	Alexandra Caillouet (b) (4)	03 Mar 2021 14:34:18

US3362083

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17
User entered 'VISIT4'	System	03 Mar 2021 14:34:18

US3362083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User closed query 'Per CDM: Thank you for the response. Since both visits occurred on the same day, it is expected to have the same information recorded. Please consider adding the vital signs information (pre-dose or post-dose) for this visit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:43:50
Query 'Per CDM: Thank you for the response. Since both visits occurred on the same day, it is expected to have the same information recorded. Please consider adding the vital signs information (pre-dose or post-dose) for this visit. ' answered with 'updated' (Site from DM).	Crystal Rowell (b) (4) (b) (4)	06 Apr 2021 22:43:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	06 Apr 2021 22:43:25
User opened query 'Per CDM: Thank you for the response. Since both visits occurred on the same day, it is expected to have the same information recorded. Please consider adding the vital signs information (pre-dose or post-dose) for this visit. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 17:39:48
User closed query 'Per CDM: Please be aware that Visit 4 Day 209 and OL-D57 took place exactly the same day. However, Vital Signs are recorded here as NO but in OL-D57 are recorded as YES. Please clarify why there is a difference or update the field. Thank you! ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 17:39:48
Query 'Per CDM: Please be aware that Visit 4 Day 209 and OL-D57 took place exactly the same day. However, Vital Signs are recorded here as NO but in OL-D57 are recorded as YES. Please clarify why there is a difference or update the field. Thank you! ' answered with 'Visit 4 Vitals not required per protocol. ' (Site from DM).	Alexandra Caillouet (b) (4)	05 Apr 2021 21:19:27

US3362083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Please be aware that Visit 4 Day 209 and OL-D57 took place exactly the same day. However, Vital Signs are recorded here as NO but in OL-D57 are recorded as YES. Please clarify why there is a difference or update the field. Thank you! ' (Site from DM). User entered 'No (N)'	(b) (4), (b) (6) [REDACTED] Alexandra Caillouet (b) (4)	05 Apr 2021 21:15:18 30 Mar 2021 18:32:23

US3362083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '3 Mar 2021' reason for change: Data Entry Error	(b) (4)	
	Crystal Rowell (b) (4)	06 Apr 2021 22:43:25
User entered empty.	(b) (4)	
	Alexandra Caillouet	30 Mar 2021 18:32:23
	(b) (4)	

US3362083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '07:42' reason for change: Data Entry Error	Crystal Rowell (b) (4)	06 Apr 2021 22:43:25
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:32:23

US3362083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17
User entered '3 Mar 2021 07:42'	System	06 Apr 2021 22:43:25
User entered empty.	System	30 Mar 2021 18:32:23

US3362083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '36.7' C reason for change: Data Entry Error	Crystal Rowell (b) (4)	06 Apr 2021 22:43:25
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:32:23

US3362083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	Crystal Rowell (b) (4)	06 Apr 2021 22:43:25
User entered empty.	(b) (4)	
	Alexandra Caillouet	30 Mar 2021 18:32:23
	(b) (4)	

US3362083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:32:23

US3362083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '58' reason for change: Data Entry Error	Crystal Rowell (b) (4)	06 Apr 2021 22:43:25
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:32:23

US3362083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17
User entered 'bpm'	System	06 Apr 2021 22:43:25
User entered empty.	System	30 Mar 2021 18:32:23

US3362083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '18' reason for change: Data Entry Error	Crystal Rowell (b) (4)	06 Apr 2021 22:43:25
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:32:23

US3362083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17
User entered 'breaths/min'	System	06 Apr 2021 22:43:25
User entered empty.	System	30 Mar 2021 18:32:23

US3362083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '103' reason for change: Data Entry Error	Crystal Rowell (b) (4)	06 Apr 2021 22:43:25
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:32:23

US3362083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17
User entered 'mmHg'	System	06 Apr 2021 22:43:25
User entered empty.	System	30 Mar 2021 18:32:23

US3362083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '64' reason for change: Data Entry Error	Crystal Rowell (b) (4)	06 Apr 2021 22:43:25
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:32:23

US3362083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17
User entered 'mmHg'	System	06 Apr 2021 22:43:25
User entered empty.	System	30 Mar 2021 18:32:23

US3362083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17

US3362083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17

US3362083

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'No (N)'	Alexandra Caillouet (b) (4)	03 Mar 2021 14:34:56

US3362083

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:02

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered empty.	Alexandra Caillouet (b) (4)	03 Mar 2021 14:34:56

US3362083

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	03 Mar 2021 14:36:41

US3362083

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '3 Mar 2021'	Alexandra Caillouet (b) (4)	03 Mar 2021 14:36:41

US3362083

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '07:45'	Alexandra Caillouet (b) (4)	03 Mar 2021 14:36:41

US3362083

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17
User entered '3 Mar 2021 07:45'	System	03 Mar 2021 14:36:41

US3362083

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	03 Mar 2021 14:36:50

US3362083

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:17
User entered 'I'	System	03 Mar 2021 14:36:50

US3362083

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:20:26

US3362083

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '1 Apr 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:20:26

US3362083

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:20:26

US3362083

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:20:26

US3362083

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:20:31

US3362083

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 14:20:31

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:35:02

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:38:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	30 Mar 2021 15:51:04
User entered '28 Sep 2020' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	29 Mar 2021 19:56:54
Query 'Data is required. Please complete.' answered with 'Data was entered in error. Corresponds to Convalescent Visit Day 28 on 28SEP2020 from Illness Visit (1). ' (Site from System).	Alexandra Caillouet (b) (4)	29 Mar 2021 19:51:53
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 19:50:31
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	29 Mar 2021 19:50:31
User entered '28 Sep 2020'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:14:21

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:35:02

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:38:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	30 Mar 2021 15:51:07
User entered '13:10' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	29 Mar 2021 19:56:54
Query 'Data is required. Please complete.' answered with 'Data was entered in error. Corresponds to Convalescent Visit Day 28 on 28SEP2020 from Illness Visit (1). ' (Site from System).	Alexandra Caillouet (b) (4)	29 Mar 2021 19:51:55
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 19:50:31
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	29 Mar 2021 19:50:31
User entered '13:10' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	14 Dec 2020 15:15:45
User entered '13:18'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:14:21

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:35:02

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:51
User entered '28 Sep 2020 13:10'	System	29 Mar 2021 19:56:54
User entered empty.	System	29 Mar 2021 19:50:31
User entered '28 Sep 2020 13:10'	System	14 Dec 2020 15:15:45
User entered '28 Sep 2020 13:18'	System	14 Dec 2020 15:14:21

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:35:02

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:38:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	30 Mar 2021 15:51:09
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	29 Mar 2021 19:56:54
Query 'Data is required. Please complete.' answered with 'Data was entered in error. Corresponds to Convalescent Visit Day 28 on 28SEP2020 from Illness Visit (1). ' (Site from System).	Alexandra Caillouet (b) (4)	29 Mar 2021 19:51:58
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 19:50:31
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	29 Mar 2021 19:50:31
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:14:21

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:35:02

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:38:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	30 Mar 2021 15:51:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	29 Mar 2021 19:56:54
Query 'Data is required. Please complete.' answered with 'Data was entered in error. Corresponds to Convalescent Visit Day 28 on 28SEP2020 from Illness Visit (1). ' (Site from System).	Alexandra Caillouet (b) (4)	29 Mar 2021 19:52:01
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 19:50:31
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	29 Mar 2021 19:50:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	14 Dec 2020 15:14:29
User entered 'No (N)'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:14:21

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint activated with code reason code Data required.	(b) (4)	29 Mar 2021 19:57:00
DataPoint inactivated with code reason code Data not required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:52:08
User entered 'Day 28 (Day 28)'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:15:29

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:38:55
DataPoint activated with code reason code Data required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:57:00
DataPoint inactivated with code reason code Data not required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:52:08
User entered '28 Sep 2020'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:15:29

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:38:55
DataPoint activated with code reason code Data required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:57:00
DataPoint inactivated with code reason code Data not required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:52:08
User entered '0'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:15:29

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:38:55
DataPoint activated with code reason code Data required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:57:00
DataPoint inactivated with code reason code Data not required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:52:08
User entered '99'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:15:29

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:55
DataPoint activated with code reason code Data required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:57:00
DataPoint inactivated with code reason code Data not required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:52:08
User entered '%'	System	14 Dec 2020 15:15:29

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:38:55
DataPoint activated with code reason code Data required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:57:00
DataPoint inactivated with code reason code Data not required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:52:08
User entered '36.8' C	Alexandra Caillouet (b) (4)	14 Dec 2020 15:15:29

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:38:55
DataPoint activated with code reason code Data required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:57:00
DataPoint inactivated with code reason code Data not required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:52:08
User entered 'None (None)'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:15:29

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:38:55
DataPoint activated with code reason code Data required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:57:00
DataPoint inactivated with code reason code Data not required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:52:08
User entered 'None (None)'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:15:29

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:38:55
DataPoint activated with code reason code Data required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:57:00
DataPoint inactivated with code reason code Data not required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:52:08
User entered 'None (None)'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:15:29

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:38:55
DataPoint activated with code reason code Data required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:57:00
DataPoint inactivated with code reason code Data not required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:52:08
User entered 'None (None)'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:15:29

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:38:55
DataPoint activated with code reason code Data required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:57:00
DataPoint inactivated with code reason code Data not required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:52:08
User entered 'None (None)'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:15:29

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:38:55
DataPoint activated with code reason code Data required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:57:00
DataPoint inactivated with code reason code Data not required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:52:08
User entered 'None (None)'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:15:29

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:38:55
DataPoint activated with code reason code Data required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:57:00
DataPoint inactivated with code reason code Data not required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:52:08
User entered 'None (None)'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:15:29

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:38:55
DataPoint activated with code reason code Data required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:57:00
DataPoint inactivated with code reason code Data not required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:52:08
User entered 'None (None)'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:15:29

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:38:55
DataPoint activated with code reason code Data required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:57:00
DataPoint inactivated with code reason code Data not required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:52:08
User entered 'None (None)'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:15:29

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:38:55
DataPoint activated with code reason code Data required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:57:00
DataPoint inactivated with code reason code Data not required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:52:08
User entered 'None (None)'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:15:29

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:38:55
DataPoint activated with code reason code Data required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:57:00
DataPoint inactivated with code reason code Data not required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:52:08
User entered 'None (None)'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:15:29

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:38:55
DataPoint activated with code reason code Data required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:57:00
DataPoint inactivated with code reason code Data not required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:52:08
User entered 'None (None)'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:15:29

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:38:55
DataPoint activated with code reason code Data required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:57:00
DataPoint inactivated with code reason code Data not required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:52:08
User entered 'None (None)'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:15:29

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:38:55
DataPoint activated with code reason code Data required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:57:00
DataPoint inactivated with code reason code Data not required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:52:08
User entered 'None (None)'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:15:29

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:38:55
DataPoint activated with code reason code Data required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:57:00
DataPoint inactivated with code reason code Data not required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:52:08
User entered 'None (None)'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:15:29

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:38:55
DataPoint activated with code reason code Data required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:57:00
DataPoint inactivated with code reason code Data not required.	Alexandra Caillouet (b) (4)	29 Mar 2021 19:52:08
User entered 'None (None)'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:15:29

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:35:02

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:59
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:39:23
User entered '28 Sep 2020'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:17:31

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:35:02

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:59
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:39:23
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:17:31

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:35:02

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:59
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:39:23
User entered 'No (N)'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:17:31

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:35:02

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:59
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:39:23
User closed query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 19:10:29
Query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' answered with 'COVID-19 Assessment 28SEP2020 folder was completed incorrectly. Please inactivate all associated pages. 28SEP2020 was Convalescence visit Day 28 which is captured under illness (1)' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	06 Mar 2021 18:43:13
User opened query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 17:54:34
User entered '28 Sep 2020'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:17:31

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:35:02

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:59
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:39:23
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:17:31

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:35:02

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:59
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:39:23
User entered empty.	Alexandra Caillouet (b) (4)	14 Dec 2020 15:17:31

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:35:02

[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)	01 May 2021 22:49:59
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:39:23
User entered 'No (N)'	Alexandra Caillouet (b) (4)	14 Dec 2020 15:17:31

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:35:02

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:59
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:39:23
User entered empty.	Alexandra Caillouet (b) (4)	14 Dec 2020 15:17:31

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:35:02

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:59
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:39:23
User entered empty.	Alexandra Caillouet (b) (4)	14 Dec 2020 15:17:31

US3362083

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:35:02

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:59
User entered '0'	System	14 Dec 2020 15:17:31

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:35:02

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User closed query 'Per GCL Lab Reconciliation requery: Swab: Per PPD portal & per response, "PCR Swab for Day 28 collected on 28 Sep 2020. Accession Number: 1F64491"; however, swab sample collected on 28 SEP 2020 is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for 28 SEP 2020 date and updating swab data in the COVID Diagnostic form, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 07:54:59
Query 'Per GCL Lab Reconciliation requery: Swab: Per PPD portal & per response, "PCR Swab for Day 28 collected on 28 Sep 2020. Accession Number: 1F64491"; however, swab sample collected on 28 SEP 2020 is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for 28 SEP 2020 date and updating swab data in the COVID Diagnostic form, else clarify.' answered with 'Day 28 Swab added.' (Site from DM).	Alexandra Caillouet (b) (4)	14 Dec 2020 15:21:49
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per PPD portal & per response, "PCR Swab for Day 28 collected on 28 Sep 2020. Accession Number: 1F64491"; however, swab sample collected on 28 SEP 2020 is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for 28 SEP 2020 date and updating swab data in the COVID Diagnostic form, else clarify.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:39:45

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:35:02

[Date of Contact](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab: Per site response on Covid diagnostic Test eCRF,' saliva not collected on 28Sep2020- no kit E available, swab collected instead of saliva since not available as stated in protocol', & per PPD portal, swab sample was collected on 28SEP2020 at Illness Visit Day 1; however, swab sample for 28SEP2020 is missing in EDC. Kindly review if swab sample for 28SEP2020 was collected, if yes, consider updating EDC by initiating new Covid -19 Assessment eCRF for the corresponding date and updating swab data in the COVID Diagnostic form, else clarify.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:39:45
Query 'Per GCL Lab Reconciliation: Swab: Per site response on Covid diagnostic Test eCRF,' saliva not collected on 28Sep2020- no kit E available, swab collected instead of saliva since not available as stated in protocol', & per PPD portal, swab sample was collected on 28SEP2020 at Illness Visit Day 1; however, swab sample for 28SEP2020 is missing in EDC. Kindly review if swab sample for 28SEP2020 was collected, if yes, consider updating EDC by initiating new Covid -19 Assessment eCRF for the corresponding date and updating swab data in the COVID Diagnostic form, else clarify.' answered with 'PCR Swab for Day 1 collected on 31 Aug 2020. PCR Swab for Day 28 collected on 28 Sep 2020. Accession Number: 1F64491' (Site from DM).	Alexandra Caillouet (b) (4)	09 Dec 2020 21:56:33
User opened query 'Per GCL Lab Reconciliation: Swab: Per site response on Covid diagnostic Test eCRF,' saliva not collected on 28Sep2020- no kit E available, swab collected instead of saliva since not available as stated in protocol', & per PPD portal, swab sample was collected on 28SEP2020 at Illness Visit Day 1; however, swab sample for 28SEP2020 is missing in EDC. Kindly review if swab sample for 28SEP2020 was collected, if yes, consider updating EDC by initiating new Covid -19 Assessment eCRF for the corresponding date and updating swab data in the COVID Diagnostic form, else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 06:53:31

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:35:02

[Date of Contact](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: it appears there are multiple Covid Assessments recorded with sequential dates. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 01:55:46
User closed query 'Per ETRTR: Please complete data entry within Illness Visit Day1 folder, Saliva collections and missing days for Symptoms Log including days prior to 31Aug20, thanks.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 04:25:08
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:36:18
Query 'Per CDM: it appears there are multiple Covid Assessments recorded with sequential dates. Please reconcile.' answered with 'per audit history the covid assessment folders for 01SEP2020 and 02SEP2020 were inactivated' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	01 Nov 2020 00:26:50
User opened query 'Per CDM: it appears there are multiple Covid Assessments recorded with sequential dates. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 12:23:46
Query 'Per ETRTR: Please complete data entry within Illness Visit Day1 folder, Saliva collections and missing days for Symptoms Log including days prior to 31Aug20, thanks.' answered with 'initial visit was 31/aug/2020' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 13:52:33
User opened query 'Per ETRTR: Please complete data entry within Illness Visit Day1 folder, Saliva collections and missing days for Symptoms Log including days prior to 31Aug20, thanks.' (Site from CRA).	(b) (4), (b) (6)	15 Sep 2020 21:51:17
Query 'Per ETRTR: Please complete data entry within Illness Visit Day1 folder, Saliva collections and missing days for Symptoms Log, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	15 Sep 2020 21:50:17
User opened query 'Per ETRTR: Please complete data entry within Illness Visit Day1 folder, Saliva collections and missing days for Symptoms Log, thanks.' (Site from CRA).	(b) (4), (b) (6)	15 Sep 2020 21:49:57
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 15:48:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 15:48:53
User entered '31 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 15:48:53

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:35:02

[Date of Contact](#)

Audit	User	Time (GMT)
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 23:24:25
User entered empty.	Crystal Rowell (b) (4) (b) (4)	31 Aug 2020 23:24:25

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:35:02

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:36:18
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 15:48:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 15:48:53
User entered '09:30' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 15:48:53
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 23:24:25
User entered empty.	Crystal Rowell (b) (4) (b) (4)	31 Aug 2020 23:24:25

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:35:02

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:23
User entered '31 Aug 2020 09:30'	System	01 Sep 2020 15:48:53
User entered empty.	System	31 Aug 2020 23:24:25

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:35:02

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:36:18
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 15:48:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 15:48:53
User entered 'Safety Call (Safety Call)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 15:48:53
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 23:24:25
User entered empty.	Crystal Rowell (b) (4) (b) (4)	31 Aug 2020 23:24:25

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:35:02

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:36:18
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 15:48:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 15:48:53
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 15:48:53
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 23:24:25
User entered empty.	Crystal Rowell (b) (4) (b) (4)	31 Aug 2020 23:24:25

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	18 Mar 2021 19:22:30
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 14:54:35
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	01 Sep 2020 15:50:26

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User closed query 'per CDM: please confirm symptom day for 31 Aug 2020, as day 3 was previously noted as 30 Aug 2020' (Site from DM).	(b) (4)	
Query 'per CDM: please confirm symptom day for 31 Aug 2020, as day 3 was previously noted as 30 Aug 2020' answered with 'confirmed 31AUG2020 was day 3 of symptoms.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 19:46:44
Query 'per CDM: please confirm symptom day for 31 Aug 2020, as day 3 was previously noted as 30 Aug 2020' answered with 'confirmed 31AUG2020 was day 3 of symptoms.' (Site from DM).	Alexandra Caillouet (b) (4)	18 Mar 2021 19:20:22
User opened query 'per CDM: please confirm symptom day for 31 Aug 2020, as day 3 was previously noted as 30 Aug 2020' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 08:58:02
User closed query 'Please reconcile as AE start date =28Aug2020. Symptom log entry per CCGs and training provided to all sites instructs that first day of symptom log is first day subject experienced symptoms. Please reconcile symptom log to match per CCG's symptom log first day entry is day symptoms first began not the date of illness visit. This must be updated and then the symptom day number of each line to be updated. Days are entered sequentially beginning with day symptoms began' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 01:08:46
Query 'Please reconcile as AE start date =28Aug2020. Symptom log entry per CCGs and training provided to all sites instructs that first day of symptom log is first day subject experienced symptoms. Please reconcile symptom log to match per CCG's symptom log first day entry is day symptoms first began not the date of illness visit. This must be updated and then the symptom day number of each line to be updated. Days are entered sequentially beginning with day symptoms began' answered with 'updated' (Site from CRA).	Crystal Rowell (b) (4)	09 Nov 2020 15:43:19

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

Date

Audit	User	Time (GMT)
User opened query 'Please reconcile as AE start date =28Aug2020. Symptom log entry per CCGs and training provided to all sites instructs that first day of symptom log is first day subject experienced symptoms. Please reconcile symptom log to match per CCG's symptom log first day entry is day symptoms first began not the date of illness visit. This must be updated and then the symptom day number of each line to be updated. Days are entered sequentially beginning with day symptoms began' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 04:24:26
	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User closed query 'Per CDM: contact date and symptom start date are the same. Please confirm this is the actual symptom start and update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 13:26:47
Query 'Per CDM: contact date and symptom start date are the same. Please confirm this is the actual symptom start and update accordingly.' answered with 'per ecrf guidelines the contact date and symptom date is the same ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 20:39:07
User opened query 'Per CDM: contact date and symptom start date are the same. Please confirm this is the actual symptom start and update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 23:49:11
User entered '31 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 15:50:26

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 15:50:26

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '97'	(b) (4), (b) (6)	01 Sep 2020 15:50:26

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User entered '%'	System	01 Sep 2020 15:50:26

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered '37' C	(b) (4), (b) (6)	01 Sep 2020 15:50:26

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'Mild (Mild)'	(b) (4), (b) (6)	01 Sep 2020 15:50:26

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	01 Sep 2020 15:50:26

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	01 Sep 2020 15:50:26

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	01 Sep 2020 15:50:26

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'Mild (Mild)'	(b) (4), (b) (6)	01 Sep 2020 15:50:26

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'Mild (Mild)'	(b) (4), (b) (6)	01 Sep 2020 15:50:26

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'Mild (Mild)'	(b) (4), (b) (6)	01 Sep 2020 15:50:26

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'Mild (Mild)'	(b) (4), (b) (6)	01 Sep 2020 15:50:26

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	01 Sep 2020 15:50:26

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	01 Sep 2020 15:50:26

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	01 Sep 2020 15:50:26

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	01 Sep 2020 15:50:26

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	01 Sep 2020 15:50:26

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	01 Sep 2020 15:50:26

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	01 Sep 2020 15:50:26

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	01 Sep 2020 15:50:26

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	18 Mar 2021 19:22:30
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 14:54:35
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	01 Sep 2020 22:00:36

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 22:00:36

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 22:00:36

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '98'	(b) (4), (b) (6)	01 Sep 2020 22:00:36

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User entered '%'	System	01 Sep 2020 22:00:36

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '97' F	(b) (4), (b) (6)	01 Sep 2020 22:00:36

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	01 Sep 2020 22:00:36

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	01 Sep 2020 22:00:36

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	01 Sep 2020 22:00:36

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	(b) (4), (b) (6)	01 Sep 2020 22:00:36

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	01 Sep 2020 22:00:36

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	01 Sep 2020 22:00:36

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	01 Sep 2020 22:00:36

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	01 Sep 2020 22:00:36

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	01 Sep 2020 22:00:36

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	01 Sep 2020 22:00:36

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	01 Sep 2020 22:00:36

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	01 Sep 2020 22:00:36

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	01 Sep 2020 22:00:36

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	01 Sep 2020 22:00:36

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	01 Sep 2020 22:00:36

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	01 Sep 2020 22:00:36

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	18 Mar 2021 19:22:30
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 14:54:35
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	02 Sep 2020 21:28:05

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 21:28:05

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 21:28:05

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '98'	(b) (4), (b) (6)	02 Sep 2020 21:28:05

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User entered '%'	System	02 Sep 2020 21:28:05

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered '96.5' F	(b) (4), (b) (6)	02 Sep 2020 21:28:05

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	02 Sep 2020 21:28:05

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	02 Sep 2020 21:28:05

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	02 Sep 2020 21:28:05

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	02 Sep 2020 21:28:05

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	02 Sep 2020 21:28:05

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	02 Sep 2020 21:28:05

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	02 Sep 2020 21:28:05

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	02 Sep 2020 21:28:05

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	02 Sep 2020 21:28:05

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	02 Sep 2020 21:28:05

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	02 Sep 2020 21:28:05

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	02 Sep 2020 21:28:05

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	02 Sep 2020 21:28:05

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	02 Sep 2020 21:28:05

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	02 Sep 2020 21:28:05

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	02 Sep 2020 21:28:05

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	18 Mar 2021 19:22:30
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 14:54:35
User entered 'Day 4 (Day 4)'	(b) (4), (b) (6)	03 Sep 2020 22:24:51

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '3 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 22:24:51

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 22:24:51

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '98'	(b) (4), (b) (6)	03 Sep 2020 22:24:51

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User entered '%'	System	03 Sep 2020 22:24:51

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered '97' F	(b) (4), (b) (6)	03 Sep 2020 22:24:51

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 22:24:51

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 22:24:51

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 22:24:51

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 22:24:51

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 22:24:51

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 22:24:51

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 22:24:51

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 22:24:51

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 22:24:51

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 22:24:51

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 22:24:51

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 22:24:51

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 22:24:51

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 22:24:51

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 22:24:51

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	03 Sep 2020 22:24:51

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	18 Mar 2021 19:22:30
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 14:54:35
User entered 'Day 5 (Day 5)'	(b) (4), (b) (6)	04 Sep 2020 19:41:16

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 19:41:16

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 19:41:16

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '97'	(b) (4), (b) (6)	04 Sep 2020 19:41:16

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User entered '%'	System	04 Sep 2020 19:41:16

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered '97.8' F	(b) (4), (b) (6)	04 Sep 2020 19:41:16

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Sep 2020 19:41:16

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Sep 2020 19:41:16

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Sep 2020 19:41:16

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Sep 2020 19:41:16

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Sep 2020 19:41:16

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Sep 2020 19:41:16

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Sep 2020 19:41:16

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Sep 2020 19:41:16

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'Severe (Severe)'	(b) (4), (b) (6)	04 Sep 2020 19:41:16

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'Severe (Severe)'	(b) (4), (b) (6)	04 Sep 2020 19:41:16

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Sep 2020 19:41:16

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Sep 2020 19:41:16

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Sep 2020 19:41:16

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Sep 2020 19:41:16

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Sep 2020 19:41:16

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Sep 2020 19:41:16

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	18 Mar 2021 19:22:30
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 14:54:35
User entered 'Day 6 (Day 6)'	Crystal Rowell (b) (4)	23 Sep 2020 19:02:55

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered '05 Sep 2020'	Crystal Rowell (b) (4)	23 Sep 2020 19:02:55

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '0'	Crystal Rowell (b) (4)	23 Sep 2020 19:02:55

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '100'	Crystal Rowell (b) (4)	23 Sep 2020 19:02:55

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User entered '%'	System	23 Sep 2020 19:02:55

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered '98.7' F	Crystal Rowell (b) (4)	23 Sep 2020 19:02:55

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:02:55

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:02:55
	Crystal Rowell (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:02:55

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	Crystal Rowell (b) (4)	23 Sep 2020 19:02:55
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:02:55

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	Crystal Rowell (b) (4)	23 Sep 2020 19:02:55
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:02:55
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:02:55
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'Moderate (Moderate)'	Crystal Rowell (b) (4)	23 Sep 2020 19:02:55

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'Moderate (Moderate)'	Crystal Rowell (b) (4)	23 Sep 2020 19:02:55

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:02:55

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	Crystal Rowell (b) (4)	23 Sep 2020 19:02:55
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:02:55

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:02:55
	Crystal Rowell (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:02:55

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:02:55

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	(b) (4) Alexandra Caillouet	18 Mar 2021 19:22:30
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	(b) (4) Crystal Rowell	09 Nov 2020 14:54:35
User entered 'Day 7 (Day 7)'	(b) (4) Crystal Rowell	23 Sep 2020 19:04:04

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered '06 Sep 2020'	Crystal Rowell (b) (4)	23 Sep 2020 19:04:04

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '0'	Crystal Rowell (b) (4)	23 Sep 2020 19:04:04

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '98'	Crystal Rowell (b) (4)	23 Sep 2020 19:04:04

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User entered '%'	System	23 Sep 2020 19:04:04

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered '97.5' F	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	Crystal Rowell (b) (4)	23 Sep 2020 19:04:04
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:04:04

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:04:04
	Crystal Rowell (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:04:04

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:04:04
	Crystal Rowell (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:04:04

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	Crystal Rowell (b) (4)	23 Sep 2020 19:04:04
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:04:04

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:04:04

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:04:04

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:04:04

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:04:04

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	Crystal Rowell (b) (4)	23 Sep 2020 19:04:04
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (7)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:04:04
	Crystal Rowell (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:04:04
	Crystal Rowell (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:04:04

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:04:04

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	(b) (4) Alexandra Caillouet	18 Mar 2021 19:22:30
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	(b) (4) Crystal Rowell (b) (4)	09 Nov 2020 14:54:35
User entered 'Day 8 (Day 8)'	(b) (4) Crystal Rowell (b) (4)	23 Sep 2020 19:06:03

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:10:21
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 19:12:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 19:12:41
User entered '07 Sep 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	23 Sep 2020 19:12:41
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 19:06:03
User entered empty.	Crystal Rowell (b) (4) (b) (4)	23 Sep 2020 19:06:03

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (8)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	
	Crystal Rowell (b) (4)	23 Sep 2020 19:12:41
User entered '0'	(b) (4)	
	Crystal Rowell (b) (4)	23 Sep 2020 19:06:03
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:03

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User entered empty.	System	23 Sep 2020 19:06:03

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:03

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:03

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 19:06:03
	Crystal Rowell (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:03

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 19:06:03

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:03

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	Crystal Rowell (b) (4)	23 Sep 2020 19:06:03
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:03

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:03

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:03

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:03

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:03

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:03

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:03

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:03

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:03

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:03

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	(b) (4) Alexandra Caillouet	18 Mar 2021 19:22:30
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	(b) (4) Crystal Rowell	09 Nov 2020 14:54:35
User entered 'Day 9 (Day 9)'	(b) (4) Crystal Rowell	23 Sep 2020 19:06:09

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:10:21
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 19:12:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 19:12:41
User entered '08 Sep 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	23 Sep 2020 19:12:41
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 19:06:09
User entered empty.	Crystal Rowell (b) (4) (b) (4)	23 Sep 2020 19:06:09

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '0'	Crystal Rowell (b) (4)	23 Sep 2020 19:06:09

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered '97' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Sep 2020 19:12:41
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:09

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User entered '%'	System	23 Sep 2020 19:12:41
User entered empty.	System	23 Sep 2020 19:06:09

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '98.6' F reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Sep 2020 19:12:41
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	23 Sep 2020 19:06:09
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 19:12:41
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:09
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Sep 2020 19:12:41
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	23 Sep 2020 19:06:09
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 19:12:41
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:09
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Sep 2020 19:12:41
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	23 Sep 2020 19:06:09
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Sep 2020 19:12:41
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:09

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Sep 2020 19:12:41
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:09

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Sep 2020 19:12:41
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:09

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Sep 2020 19:12:41
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:09

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 19:12:41
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:09
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Sep 2020 19:12:41
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:09

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 19:12:41
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:09
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Sep 2020 19:12:41
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:09

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 19:12:41
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:09
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Sep 2020 19:12:41
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	23 Sep 2020 19:06:09
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Sep 2020 19:12:41
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	23 Sep 2020 19:06:09
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Sep 2020 19:12:41
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:09

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	(b) (4) Alexandra Caillouet	18 Mar 2021 19:22:30
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	(b) (4) Crystal Rowell (b) (4)	09 Nov 2020 14:54:35
User entered 'Day 10 (Day 10)'	(b) (4) Crystal Rowell (b) (4)	23 Sep 2020 19:06:15

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:10:21
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 19:12:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 19:12:41
User entered '09 Sep 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	23 Sep 2020 19:12:41
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 19:06:15
User entered empty.	Crystal Rowell (b) (4) (b) (4)	23 Sep 2020 19:06:15

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '0'	Crystal Rowell (b) (4)	23 Sep 2020 19:06:15

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered '97' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Sep 2020 19:12:41
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:15

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User entered '%'	System	23 Sep 2020 19:12:41
User entered empty.	System	23 Sep 2020 19:06:15

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered '97' F reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Sep 2020 19:12:41
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:15

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Sep 2020 19:12:41
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	23 Sep 2020 19:06:15
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Sep 2020 19:12:41
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:15

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Sep 2020 19:12:41
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:15

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Sep 2020 19:12:41
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	23 Sep 2020 19:06:15
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Sep 2020 19:12:41
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:15

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Sep 2020 19:12:41
User entered empty.	(b) (4) Crystal Rowell (b) (4) (b) (4)	23 Sep 2020 19:06:15

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 19:12:41
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:15
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 19:12:41
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:15
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 19:12:41
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:15
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 19:12:41
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:15
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Sep 2020 19:12:41
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	23 Sep 2020 19:06:15
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Sep 2020 19:12:41
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:15

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Sep 2020 19:12:41
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	23 Sep 2020 19:06:15
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Sep 2020 19:12:41
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	23 Sep 2020 19:06:15
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Sep 2020 19:12:41
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	23 Sep 2020 19:06:15
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 19:12:41
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:06:15
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	(b) (4) Alexandra Caillouet	18 Mar 2021 19:23:16
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	(b) (4) Crystal Rowell	09 Nov 2020 15:02:19
User entered 'Day 11 (Day 11)'	(b) (4) Crystal Rowell	23 Sep 2020 19:15:45

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered '10 Sep 2020'	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '0'	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '97'	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User entered '%'	System	23 Sep 2020 19:15:45

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered '97.0' F	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:15:45
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:15:45
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:15:45
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:15:45
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:15:45
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User entered 'Day 15 (Day 15)' reason for change: Data Entry Error	(b) (4) Alexandra Caillouet	18 Mar 2021 19:23:16
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	(b) (4) Crystal Rowell	09 Nov 2020 15:02:19
User entered 'Day 12 (Day 12)'	(b) (4) Crystal Rowell	23 Sep 2020 19:15:45

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered '11 Sep 2020'	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '0'	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '98'	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User entered '%'	System	23 Sep 2020 19:15:45

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered '97.6' F	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:15:45
	Crystal Rowell (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (12)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:15:45
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:15:45
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:15:45
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:15:45
	Crystal Rowell (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:15:45
	Crystal Rowell (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:15:45
	Crystal Rowell (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:15:45

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User entered 'Day 16 (Day 16)' reason for change: Data Entry Error	(b) (4) Alexandra Caillouet	18 Mar 2021 19:23:16
User entered 'Day 15 (Day 15)' reason for change: Data Entry Error	(b) (4) Crystal Rowell	09 Nov 2020 15:02:19
User entered 'Day 13 (Day 13)'	(b) (4) Crystal Rowell	23 Sep 2020 19:23:56

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered '12 Sep 2020'	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	Crystal Rowell (b) (4)	23 Sep 2020 19:23:56
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '0'	Crystal Rowell (b) (4)	23 Sep 2020 19:23:56

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered '98'	Crystal Rowell (b) (4)	23 Sep 2020 19:23:56

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User entered '%'	System	23 Sep 2020 19:23:56

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '97.6' F	Crystal Rowell (b) (4)	23 Sep 2020 19:23:56

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:02

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User closed query 'Per CDM: Some assessments are not done, please consider adding missing data or if there is not data available then please consider selecting "Not Done". Thank you!' (Site from DM).	(b) (4)	05 Feb 2021 17:43:19
Query 'Per CDM: Some assessments are not done, please consider adding missing data or if there is not data available then please consider selecting "Not Done". Thank you!' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	
Query 'Per CDM: Some assessments are not done, please consider adding missing data or if there is not data available then please consider selecting "Not Done". Thank you!' answered with 'updated' (Site from DM).	Amy Thomassie (b) (4)	04 Feb 2021 17:58:40
	(b) (4)	
User opened query 'Per CDM: Some assessments are not done, please consider adding missing data or if there is not data available then please consider selecting "Not Done". Thank you!' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 10:07:05
Query 'Per CDM: Some assessments are not done, please consider adding missing data or if there is not data available then please consider selecting "Not Done". Thank you' canceled (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 10:06:59
User opened query 'Per CDM: Some assessments are not done, please consider adding missing data or if there is not data available then please consider selecting "Not Done". Thank you' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 10:06:57
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:23:56
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:23:56
	Crystal Rowell (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	Crystal Rowell (b) (4)	23 Sep 2020 19:23:56
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:23:56
	Crystal Rowell (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:23:56
	Crystal Rowell (b) (4)	
	(b) (4)	

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Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	Crystal Rowell (b) (4)	23 Sep 2020 19:23:56
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:23:56
	Crystal Rowell (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	Crystal Rowell (b) (4)	23 Sep 2020 19:23:56
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:23:56

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:23:56

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	Crystal Rowell (b) (4)	23 Sep 2020 19:23:56
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (13)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:23:56

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (13)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:23:56
	Crystal Rowell (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	Crystal Rowell (b) (4)	23 Sep 2020 19:23:56
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:25:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Un-verified.	(b) (4)	
	Amy Thomassie (b) (4)	04 Feb 2021 17:58:28
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Feb 2021 17:58:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:23:56
	(b) (4)	

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Form: Symptom Log (13)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:25:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Un-verified.	(b) (4)	
	Amy Thomassie (b) (4)	04 Feb 2021 17:58:28
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Feb 2021 17:58:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:23:56
	(b) (4)	

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User entered 'Day 17 (Day 17)' reason for change: Data Entry Error	(b) (4) Alexandra Caillouet	18 Mar 2021 19:23:16
User entered 'Day 16 (Day 16)' reason for change: Data Entry Error	(b) (4) Crystal Rowell (b) (4)	09 Nov 2020 15:02:19
User entered 'Day 14 (Day 14)'	(b) (4) Crystal Rowell (b) (4)	23 Sep 2020 19:24:46

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered '13 Sep 2020'	Crystal Rowell (b) (4)	23 Sep 2020 19:24:46

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'I'	Crystal Rowell (b) (4)	23 Sep 2020 19:24:46

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:24:46

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (14)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User entered empty.	System	23 Sep 2020 19:24:46

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 19:24:46
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 19:24:46

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 19:24:46

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:24:46

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 19:24:46

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:24:46

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	Crystal Rowell (b) (4)	23 Sep 2020 19:24:46
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 19:24:46
	Crystal Rowell (b) (4)	
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 19:24:46

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:24:46

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:24:46

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	Crystal Rowell (b) (4)	23 Sep 2020 19:24:46
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:24:46

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:24:46

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 19:24:46

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 19:24:46
	Crystal Rowell (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	Crystal Rowell (b) (4)	23 Sep 2020 19:24:46
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User entered 'Day 18 (Day 18)' reason for change: Data Entry Error	(b) (4) Alexandra Caillouet	18 Mar 2021 19:23:16
User entered 'Day 17 (Day 17)' reason for change: Data Entry Error	(b) (4) Crystal Rowell	09 Nov 2020 15:02:19
User entered 'Day 15 (Day 15)'	(b) (4) Crystal Rowell	23 Sep 2020 19:25:38

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User closed query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 28SEP2020. Please reconcile or clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:51:07
Query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 28SEP2020. Please reconcile or clarify.' answered with 'per protocol, patient followed for symptoms until day 14 or until symptoms resolved' (Site from DM).	Crystal Rowell (b) (4) (b) (4)	09 Nov 2020 15:42:53
User opened query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 28SEP2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 03:44:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '14 Sep 2020'	Crystal Rowell (b) (4) (b) (4)	23 Sep 2020 19:25:38

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '0'	Crystal Rowell (b) (4)	23 Sep 2020 19:25:38

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered '99'	Crystal Rowell (b) (4)	23 Sep 2020 19:25:38

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User entered '%'	System	23 Sep 2020 19:25:38

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered '97.6' F	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	Crystal Rowell (b) (4)	23 Sep 2020 19:25:38
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:25:38
	Crystal Rowell (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:25:38

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:25:38

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:25:38
	Crystal Rowell (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:25:38

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:25:38

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	Crystal Rowell (b) (4)	23 Sep 2020 19:25:38
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:25:38
	Crystal Rowell (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:25:38

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:25:38

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:25:38

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:10:21
	Crystal Rowell (b) (4)	23 Sep 2020 19:25:38
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:25:38

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:25:38
	Crystal Rowell (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:10:21
User entered 'None (None)'	Crystal Rowell (b) (4)	23 Sep 2020 19:25:38

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:10:21
User entered 'None (None)'	(b) (4), (b) (6)	23 Sep 2020 19:25:38
	Crystal Rowell (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User entered 'Day 2 (Day 2)' reason for change:	Crystal Rowell (b) (4)	09 Nov 2020 15:45:46
Data Entry Error	(b) (4)	
User entered 'Day 1 (Day 1)'	Crystal Rowell (b) (4)	09 Nov 2020 14:53:20
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	18 Nov 2020 21:12:01
User entered '29 Aug 2020'	Crystal Rowell (b) (4)	09 Nov 2020 14:53:20

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered '0'	Crystal Rowell (b) (4)	09 Nov 2020 14:53:20

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:25:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User closed query 'Per CDM: It appears that O2 Saturation and temperature are missing. If not collected, please consider recording these as Not Done.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 11:10:40
Query 'Per CDM: It appears that O2 Saturation and temperature are missing. If not collected, please consider recording these as Not Done.' answered with 'updated' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	08 Jan 2021 20:07:39
DataPoint Un-verified.	Amy Thomassie (b) (4) (b) (4)	08 Jan 2021 20:07:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Amy Thomassie (b) (4) (b) (4)	08 Jan 2021 20:07:32
User opened query 'Per CDM: It appears that O2 Saturation and temperature are missing. If not collected, please consider recording these as Not Done.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 10:10:23
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered empty.	Crystal Rowell (b) (4) (b) (4)	09 Nov 2020 14:53:20

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User entered '%'	System	08 Jan 2021 20:07:32
User entered empty.	System	09 Nov 2020 14:53:20

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:25:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Un-verified.	(b) (4)	
	Amy Thomassie (b) (4)	08 Jan 2021 20:07:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Jan 2021 20:07:32
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered empty.	Crystal Rowell (b) (4)	09 Nov 2020 14:53:20
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	18 Nov 2020 21:12:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	Crystal Rowell (b) (4)	09 Nov 2020 14:53:20

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 14:53:20
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	18 Nov 2020 21:12:01
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	Crystal Rowell (b) (4)	09 Nov 2020 14:53:20

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 14:53:20
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 14:53:20
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 14:53:20
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 14:53:20
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 14:53:20
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 14:53:20
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 14:53:20
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 14:53:20
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	18 Nov 2020 21:12:01
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	Crystal Rowell (b) (4)	09 Nov 2020 14:53:20

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 14:53:20
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 14:53:20
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 14:53:20
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 14:53:20
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:45:51
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 14:53:58
User entered 'Day 3 (Day 3)'	Crystal Rowell (b) (4)	09 Nov 2020 14:53:41

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	18 Nov 2020 21:12:01
User entered '30 Aug 2020'	Crystal Rowell (b) (4)	09 Nov 2020 14:53:41

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered '0'	Crystal Rowell (b) (4)	09 Nov 2020 14:53:41

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:25:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User closed query 'Per CDM: It appears that O2 Saturation and temperature are missing. If not collected, please consider recording these as Not Done.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 11:10:44
Query 'Per CDM: It appears that O2 Saturation and temperature are missing. If not collected, please consider recording these as Not Done.' answered with 'updated' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	08 Jan 2021 20:07:59
DataPoint Un-verified.	Amy Thomassie (b) (4) (b) (4)	08 Jan 2021 20:07:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Amy Thomassie (b) (4) (b) (4)	08 Jan 2021 20:07:52
User opened query 'Per CDM: It appears that O2 Saturation and temperature are missing. If not collected, please consider recording these as Not Done.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 10:11:21
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered empty.	Crystal Rowell (b) (4) (b) (4)	09 Nov 2020 14:53:41

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User entered '%'	System	08 Jan 2021 20:07:52
User entered empty.	System	09 Nov 2020 14:53:41

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:25:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Un-verified.	(b) (4)	
	Amy Thomassie (b) (4)	08 Jan 2021 20:07:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Jan 2021 20:07:52
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered empty.	Crystal Rowell (b) (4)	09 Nov 2020 14:53:41
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:52:33
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 14:53:41
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	18 Nov 2020 21:12:01
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:52:33
User entered empty.	Crystal Rowell (b) (4)	09 Nov 2020 14:53:41

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:52:33
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 14:53:41
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	18 Nov 2020 21:12:01
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 15:52:33
User entered empty.	Crystal Rowell (b) (4)	09 Nov 2020 14:53:41
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:52:33
User entered empty.	(b) (4) Crystal Rowell (b) (4) (b) (4)	09 Nov 2020 14:53:41

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:52:33
User entered empty.	(b) (4) Crystal Rowell (b) (4) (b) (4)	09 Nov 2020 14:53:41

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:52:33
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 14:53:41
	(b) (4)	

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:52:33
User entered empty.	(b) (4) Crystal Rowell (b) (4) (b) (4)	09 Nov 2020 14:53:41

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	18 Nov 2020 21:12:01
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:52:33
User entered empty.	Crystal Rowell (b) (4)	09 Nov 2020 14:53:41

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	18 Nov 2020 21:12:01
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:52:33
User entered empty.	Crystal Rowell (b) (4)	09 Nov 2020 14:53:41

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:52:33
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 14:53:41
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:52:33
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 14:53:41
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:52:33
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 14:53:41
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:52:33
User entered empty.	(b) (4) Crystal Rowell (b) (4) (b) (4)	09 Nov 2020 14:53:41

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:52:33
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 14:53:41
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	18 Nov 2020 21:12:01
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:52:33
User entered empty.	Crystal Rowell (b) (4)	09 Nov 2020 14:53:41

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User entered 'Day 1 (Day 1)'	Crystal Rowell (b) (4)	09 Nov 2020 15:46:24

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered '28 Aug 2020'	Crystal Rowell (b) (4)	09 Nov 2020 15:46:24

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered '0'	Crystal Rowell (b) (4)	09 Nov 2020 15:46:24

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:25:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User closed query 'Per CDM: It appears that O2 Saturation is missing. If not collected, please consider recording this as Not Done.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 11:10:53
Query 'Per CDM: It appears that O2 Saturation is missing. If not collected, please consider recording this as Not Done.' answered with 'updated' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	08 Jan 2021 20:08:26
DataPoint Un-verified.	Amy Thomassie (b) (4) (b) (4)	08 Jan 2021 20:08:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Amy Thomassie (b) (4) (b) (4)	08 Jan 2021 20:08:17
User opened query 'Per CDM: It appears that O2 Saturation is missing. If not collected, please consider recording this as Not Done.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 10:11:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered empty.	Crystal Rowell (b) (4) (b) (4)	09 Nov 2020 15:46:24

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User entered '%'	System	08 Jan 2021 20:08:17
User entered empty.	System	09 Nov 2020 15:46:24

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered '99' F reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4) Crystal Rowell (b) (4) (b) (4)	09 Nov 2020 15:46:24

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 15:46:24
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 15:46:24
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 15:46:24
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 15:46:24
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 15:46:24
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4) Crystal Rowell (b) (4) (b) (4)	09 Nov 2020 15:46:24

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4) Crystal Rowell (b) (4) (b) (4)	09 Nov 2020 15:46:24

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 15:46:24
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 15:46:24
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4) Crystal Rowell (b) (4) (b) (4)	09 Nov 2020 15:46:24

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 15:46:24
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	18 Nov 2020 21:12:01
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	Crystal Rowell (b) (4)	09 Nov 2020 15:46:24

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 15:46:24
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 15:46:24
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 15:46:24
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:12:01
User entered 'None (None)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 15:51:05
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	09 Nov 2020 15:46:24
	(b) (4)	

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:35:02

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User closed query 'Per GCL Lab Recon re-query: response noted. However saliva sample collected on 28Sep2020 is not yet entered in EDC. Please reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 08:22:41
Query 'Per GCL Lab Recon re-query: response noted. However saliva sample collected on 28Sep2020 is not yet entered in EDC. Please reconcile.' answered with 'saliva not collected on 28Sep2020- no kit E available, swab collected instead of saliva since not available as stated in protocol' (Site from DM).	Crystal Rowell (b) (4) (b) (4)	19 Nov 2020 12:53:23
User opened query 'Per GCL Lab Recon re-query: response noted. However saliva sample collected on 28Sep2020 is not yet entered in EDC. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 12:49:53
User closed query 'Per GCL Lab Recon: GCL has a Swab samples with date of 31AUG2020 and 28SEP2020. Please reconcile or clarify' (Site from DM).		19 Nov 2020 12:49:53
DataPoint Verified.		04 Nov 2020 19:21:02
Query 'Per GCL Lab Recon: GCL has a Swab samples with date of 31AUG2020 and 28SEP2020. Please reconcile or clarify' answered with 'subject had nasal swab performed on 31aug2020; saliva was submitted on 28sep2020' (Site from DM).		02 Nov 2020 18:53:34
User opened query 'Per GCL Lab Recon: GCL has a Swab samples with date of 31AUG2020 and 28SEP2020. Please reconcile or clarify' (Site from DM).		25 Oct 2020 12:25:53
User entered '31 Aug 2020'		01 Sep 2020 15:55:42

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:35:02

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:21:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 15:55:42

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:35:02

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:21:02
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	10 Sep 2020 19:18:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Sep 2020 11:22:36
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 'confirmed as positive ' (Site from System).	Amy Thomassie (b) (4) (b) (4)	05 Sep 2020 15:54:55
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	05 Sep 2020 15:40:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	05 Sep 2020 15:40:08
Query 'Data is required. Please complete.' answered with 'pending results ' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 22:01:33
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 15:55:42
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 15:55:42

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:35:02

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:21:02
User entered '31 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 15:55:42

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:35:02

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:02
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	01 Sep 2020 15:55:42

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:35:02

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:21:02
User closed query 'Type of Test performed is not Other, however, Specify is provided. Please review and reconcile.' (Site from System).	System	01 Sep 2020 15:56:02
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 15:56:02
User opened query 'Type of Test performed is not Other, however, Specify is provided. Please review and reconcile.' (Site from System).	System	01 Sep 2020 15:55:42
User entered 'subject reported testing positive at local urgent care'	(b) (4), (b) (6)	01 Sep 2020 15:55:42

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[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)	01 May 2021 22:49:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:21:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 22:01:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 15:55:42

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:21:02
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 22:01:54
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 15:55:42
User entered empty.	System	01 Sep 2020 15:55:42

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:35
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:21:02
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 22:01:54
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 15:55:42
User entered empty.	System	01 Sep 2020 15:55:42

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:35
User entered 'I'	System	05 Sep 2020 15:40:08

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Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered 'No (N)'	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered empty.	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered empty.	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered empty.	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

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Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered 'No (N)'	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered empty.	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered empty.	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered empty.	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

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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)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered 'No (N)'	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

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[Start Date](#)

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DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered empty.	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

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[End Date](#)

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User entered empty.	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
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User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered empty.	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

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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)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered 'No (N)'	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

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DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered empty.	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

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[PaO2](#)

Audit	User	Time (GMT)
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User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered empty.	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered 'No (N)'	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

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DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered empty.	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered 'No (N)'	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

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DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered empty.	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

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[High-Flow Oxygen?](#)

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Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered 'No (N)'	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

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Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
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DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered empty.	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered empty.	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered 'No (N)'	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered empty.	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered empty.	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered 'No (N)'	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
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[End Date](#)

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User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
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[ECMO?](#)

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

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Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
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[Evidence of Shock Requires
Vasopressors](#)

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Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
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[Acute Renal Dysfunction?](#)

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Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
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[Hepatic Dysfunction?](#)

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Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
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User entered empty.	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:02

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered 'No (N)'	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:02

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered empty.	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:02

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered 'No (N)'	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:02

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered empty.	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:02

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered 'No (N)'	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:02

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered empty.	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:02

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered 'No (N)'	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:02

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered empty.	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:02

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:39
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:21:20
User entered empty.	Jordan Whatley (b) (4)	09 Sep 2020 22:16:15

US3362083

Folder: Covid-19 Assessment 31 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:35:02

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:21:35
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Sep 2020 19:01:27
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	01 Sep 2020 16:03:45

US3362083

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:35:02

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:50
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02,04,06,13,20SEP2020 is recorded under Illness Visit Day 3,5,7,14,21 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.'	(b) (4), (b) (6)	09 Dec 2020 06:18:21
' (Site from DM). Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02,04,06,13,20SEP2020 is recorded under Illness Visit Day 3,5,7,14,21 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.'	Alexandra Caillouet (b) (4)	04 Dec 2020 17:33:04
' answered with 'Accession Number: 1F64491 ' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02,04,06,13,20SEP2020 is recorded under Illness Visit Day 3,5,7,14,21 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.'	(b) (4), (b) (6)	04 Dec 2020 05:56:10
' (Site from DM). User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	02 Nov 2020 21:16:02

US3362083

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:35:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:50
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:33:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Nov 2020 21:16:02

US3362083

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:35:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:50
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User closed query 'Per GCL Lab Recon: Saliva: Per Preclarus report, there seems to be a data entry error in 'PPD GCL' records for this Day 3,5,7,9,14 & 21 Saliva samples collection dates as all are recorded as collected on a single day only, i.e on "08 SEP 2020", which seems to be a data entry error. Please kindly send a DCF to PPD GCL to update the correct sample collection dates in Preclarus PPD portal. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 03:57:49
Query 'Per GCL Lab Recon: Saliva: Per Preclarus report, there seems to be a data entry error in 'PPD GCL' records for this Day 3,5,7,9,14 & 21 Saliva samples collection dates as all are recorded as collected on a single day only, i.e on "08 SEP 2020", which seems to be a data entry error. Please kindly send a DCF to PPD GCL to update the correct sample collection dates in Preclarus PPD portal. Thank you.' answered with 'DCR form sent to PPD for updating ' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	27 Feb 2021 13:04:11
User opened query 'Per GCL Lab Recon: Saliva: Per Preclarus report, there seems to be a data entry error in 'PPD GCL' records for this Day 3,5,7,9,14 & 21 Saliva samples collection dates as all are recorded as collected on a single day only, i.e on "08 SEP 2020", which seems to be a data entry error. Please kindly send a DCF to PPD GCL to update the correct sample collection dates in Preclarus PPD portal. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 13:22:51
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:33:46
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Nov 2020 21:16:02

US3362083

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:35:02

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:50
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	02 Nov 2020 21:16:02

US3362083

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:35:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:50
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:33:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Nov 2020 21:16:02

US3362083

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:35:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:50
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:33:46
User entered '4 Sep 2020'	(b) (4), (b) (6)	02 Nov 2020 21:16:02

US3362083

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:35:02

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:50
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	02 Nov 2020 21:16:02

US3362083

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:35:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:50
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	04 Nov 2020 19:33:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Nov 2020 21:16:02

US3362083

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:35:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:50
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:23:08
User closed query 'Per CDM: Please confirm the Month "AUG" recorded for Day 7, Day 9, DAY 14, Day 21 and DAY 28 as all the Saliva collection date is prior to the illness visit Day1 visit date 31Aug2020.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 13:27:07
Query 'Per CDM: Please confirm the Month "AUG" recorded for Day 7, Day 9, DAY 14, Day 21 and DAY 28 as all the Saliva collection date is prior to the illness visit Day1 visit date 31Aug2020.' answered with 'date updated' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 18:19:09
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 18:18:46
User entered '6 Sep 2020' reason for change: Data Entry Error		10 Nov 2020 18:18:46
User opened query 'Per CDM: Please confirm the Month "AUG" recorded for Day 7, Day 9, DAY 14, Day 21 and DAY 28 as all the Saliva collection date is prior to the illness visit Day1 visit date 31Aug2020.' (Site from DM).		09 Nov 2020 05:09:41
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:33:46
User entered '6 Aug 2020'	(b) (4), (b) (6)	02 Nov 2020 21:16:02

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:35:02

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:50
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	02 Nov 2020 21:16:02

US3362083

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:35:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:50
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:33:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Nov 2020 21:16:02

US3362083

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:35:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:50
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08AUG2020 is recorded under Illness Visit Day 9 visit in EDC, however the sample is reported with date 08SEP2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 12:52:09
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:23:30
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08AUG2020 is recorded under Illness Visit Day 9 visit in EDC, however the sample is reported with date 08SEP2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'date updated' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 18:19:36
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 18:18:46
User entered '8 Sep 2020' reason for change: Data Entry Error		10 Nov 2020 18:18:46
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08AUG2020 is recorded under Illness Visit Day 9 visit in EDC, however the sample is reported with date 08SEP2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).		09 Nov 2020 05:04:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:33:46
User entered '8 Aug 2020'	(b) (4), (b) (6)	02 Nov 2020 21:16:02

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:35:02

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:50
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	02 Nov 2020 21:16:02

US3362083

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:35:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:50
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:33:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Nov 2020 21:16:02

US3362083

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:35:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:50
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:23:59
DataPoint Un-verified.		10 Nov 2020 18:18:46
User entered '13 Sep 2020' reason for change: Data Entry Error		10 Nov 2020 18:18:46
DataPoint Verified.		04 Nov 2020 19:33:46
User entered '13 Aug 2020'		02 Nov 2020 21:16:02

US3362083

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:35:02

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:50
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	02 Nov 2020 21:16:02

US3362083

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:35:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:50
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:33:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Nov 2020 21:16:02

US3362083

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:35:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:50
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:25:41
DataPoint Un-verified.		10 Nov 2020 18:18:46
User entered '20 Sep 2020' reason for change: Data Entry Error		10 Nov 2020 18:18:46
DataPoint Verified.		04 Nov 2020 19:33:46
User entered '20 Aug 2020'		02 Nov 2020 21:16:02

US3362083

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:35:02

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:50
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	02 Nov 2020 21:16:02

US3362083

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:35:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:50
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:42:05
User entered 'No (N)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	29 Jan 2021 21:08:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	22 Jan 2021 21:39:09
DataPoint Un-verified.	Crystal Rowell (b) (4) (b) (4)	19 Nov 2020 12:52:23
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	19 Nov 2020 12:52:23
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:33:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Nov 2020 21:16:02

US3362083

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:35:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:50
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:42:05
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27SEP2020 is recorded under Illness Visit Day 28 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)	22 Feb 2021 10:03:16
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27SEP2020 is recorded under Illness Visit Day 28 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 'Day 1 Illness kit was used accidentally for Day 28 Illness. No additional saliva collected for Day 28. ' (Site from DM).	Alexandra Caillouet (b) (4)	29 Jan 2021 21:08:19
DataPoint Un-verified.	Alexandra Caillouet (b) (4)	29 Jan 2021 21:08:14
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	29 Jan 2021 21:08:14
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27SEP2020 is recorded under Illness Visit Day 28 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 04:44:41
User closed query 'Per CDM: Was Saliva Collected? is noted as NO however Date of Collection is recorded. Please review and update accordingly. else clarify.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 17:04:30

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EAB) (1725)

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:35:02

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per CDM: Was Saliva Collected?' is noted as NO however Date of Collection is recorded. Please review and update accordingly. else clarify.'	Alexandra Caillouet	22 Jan 2021 21:39:25
answered with 'updated' (Site from DM).	(b) (4)	
User opened query 'Per CDM: Was Saliva Collected?' is noted as NO however Date of Collection is recorded. Please review and update accordingly. else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 09:19:55
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:25:45
DataPoint Un-verified.		10 Nov 2020 18:18:46
User entered '27 Sep 2020' reason for change: Data Entry Error		10 Nov 2020 18:18:46
DataPoint Verified.		04 Nov 2020 19:33:46
User entered '27 Aug 2020'		02 Nov 2020 21:16:02

US3362083

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:13
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 19:36:02
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	23 Sep 2020 18:57:37
	(b) (4)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:13
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	23 Sep 2020 19:36:02
User entered '31 Aug 2020'	Crystal Rowell (b) (4)	23 Sep 2020 18:57:37

US3362083

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:13
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	23 Sep 2020 19:36:02
User entered 'Clinic (Clinic)'	Crystal Rowell (b) (4)	23 Sep 2020 18:57:37

US3362083

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:13
User entered 'SICKD1'	System	23 Sep 2020 18:57:37

US3362083

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	23 Sep 2020 19:36:11
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	23 Sep 2020 18:59:33
	(b) (4)	

US3362083

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	23 Sep 2020 19:36:11
User entered '31 Aug 2020'	Crystal Rowell (b) (4)	23 Sep 2020 18:59:33

US3362083

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	23 Sep 2020 19:36:11
User entered '11:34'	Crystal Rowell (b) (4)	23 Sep 2020 18:59:33
	(b) (4)	

US3362083

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:23
User entered '31 Aug 2020 11:34'	System	23 Sep 2020 18:59:33

US3362083

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	23 Sep 2020 19:36:11
User entered '37' C	Crystal Rowell (b) (4)	23 Sep 2020 18:59:33
	(b) (4)	

US3362083

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	23 Sep 2020 19:36:11
User entered 'Oral (Oral)'	Crystal Rowell (b) (4)	23 Sep 2020 18:59:33
	(b) (4)	

US3362083

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 19:36:11
User entered empty.	Crystal Rowell (b) (4)	23 Sep 2020 18:59:33
	(b) (4)	

US3362083

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	23 Sep 2020 19:36:11
User entered '92'	Crystal Rowell (b) (4)	23 Sep 2020 18:59:33
	(b) (4)	

US3362083

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:23
User entered 'bpm'	System	23 Sep 2020 18:59:33

US3362083

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	23 Sep 2020 19:36:11
User entered '18'	Crystal Rowell (b) (4)	23 Sep 2020 18:59:33
	(b) (4)	

US3362083

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:23
User entered 'breaths/min'	System	23 Sep 2020 18:59:33

US3362083

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	23 Sep 2020 19:36:11
User entered '99'	Crystal Rowell (b) (4)	23 Sep 2020 18:59:33
	(b) (4)	

US3362083

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:23
User entered 'mmHg'	System	23 Sep 2020 18:59:33

US3362083

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	23 Sep 2020 19:36:11
User entered '62'	Crystal Rowell (b) (4)	23 Sep 2020 18:59:33
	(b) (4)	

US3362083

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:23
User entered 'mmHg'	System	23 Sep 2020 18:59:33

US3362083

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:23

US3362083

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:23

US3362083

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:34
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	23 Sep 2020 19:36:17
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	23 Sep 2020 18:59:53

US3362083

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:34
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	23 Sep 2020 19:36:17
User entered '31 Aug 2020'	Crystal Rowell (b) (4)	23 Sep 2020 18:59:53

US3362083

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:35:02

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User closed query 'Per GCL Lab Recon: GCL has Saliva Day 9 with date of 08SEP2020; however Saliva Log is not completed. Please reconcile or clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 06:12:08
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 31 AUG 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 10:38:54
Query 'Per GCL Lab Recon: GCL has Saliva Day 9 with date of 08SEP2020; however Saliva Log is not completed. Please reconcile or clarify' answered with 'UPDATED IN SILVA LOG ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 21:20:26
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 31 AUG 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'date entered was incorrect; day 1 illness was on 31aug2020; serum sample was collected on 31aug2020' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 18:40:46
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 31 AUG 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:11:35
User opened query 'Per GCL Lab Recon: GCL has Saliva Day 9 with date of 08SEP2020; however Saliva Log is not completed. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 12:26:56

US3362083

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:35:02

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:36:25
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	23 Sep 2020 19:00:10

US3362083

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:35:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:11:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User closed query 'Per GCL Lab Reconciliation: Please confirm date of immunologic sample collection as date is discrepant with date of illness visit' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 12:51:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:48:45
Query 'Per GCL Lab Reconciliation: Please confirm date of immunologic sample collection as date is discrepant with date of illness visit' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 18:38:52
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 18:38:45
User entered '31 Aug 2020' reason for change: Data Entry Error		02 Nov 2020 18:38:45
User opened query 'Per GCL Lab Reconciliation: Please confirm date of immunologic sample collection as date is discrepant with date of illness visit' (Site from DM).		30 Oct 2020 10:12:04
DataPoint Verified.		23 Sep 2020 19:36:25
User entered '23 Sep 2020'	Crystal Rowell (b) (4) (b) (4)	23 Sep 2020 19:00:10

US3362083

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:15:49
User entered 'Yes (Y)'		13 Oct 2020 21:17:31
DataPoint activated with code reason code Data required.		08 Oct 2020 18:44:09
DataPoint inactivated with code reason code Data not required.		08 Oct 2020 18:42:24

US3362083

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:15:49
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	02 Nov 2020 20:42:26
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	02 Nov 2020 20:40:54
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 21:17:31
DataPoint activated with code reason code Data required.		08 Oct 2020 18:44:09
DataPoint inactivated with code reason code Data not required.		08 Oct 2020 18:42:24

US3362083

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:15:49
User entered 'Clinic (Clinic)'		13 Oct 2020 21:17:31
DataPoint activated with code reason code Data required.		08 Oct 2020 18:44:09
DataPoint inactivated with code reason code Data not required.		08 Oct 2020 18:42:24

US3362083

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:55
User entered 'SICKD28'	System	13 Oct 2020 21:17:31
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Oct 2020 18:44:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Oct 2020 18:42:24

US3362083

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:16:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 21:18:20

US3362083

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:16:18
User closed query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	02 Nov 2020 20:42:26
User opened query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	02 Nov 2020 20:40:54
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 21:18:20

US3362083

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:16:18
User entered '13:15'	(b) (4), (b) (6)	13 Oct 2020 21:18:20

US3362083

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:55
User entered '28 Sep 2020 13:15'	System	13 Oct 2020 21:18:20

US3362083

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:16:18
User entered '36.8' C	(b) (4), (b) (6)	13 Oct 2020 21:18:20

US3362083

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:16:18
User entered 'Oral (Oral)'	(b) (4), (b) (6)	13 Oct 2020 21:18:20

US3362083

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:16:18
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 21:18:20

US3362083

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:16:18
User entered '69'	(b) (4), (b) (6)	13 Oct 2020 21:18:20

US3362083

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:55
User entered 'bpm'	System	13 Oct 2020 21:18:20

US3362083

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:16:18
User entered '18'	(b) (4), (b) (6)	13 Oct 2020 21:18:20

US3362083

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:55
User entered 'breaths/min'	System	13 Oct 2020 21:18:20

US3362083

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:16:18
User entered '108'	(b) (4), (b) (6)	13 Oct 2020 21:18:20

US3362083

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:55
User entered 'mmHg'	System	13 Oct 2020 21:18:20

US3362083

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:16:18
User closed query 'Per CDM: Please indicate if diastolic blood pressure is considered NCS or CS and report AE if applicable. Thank you' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 19:11:20
Query 'Per CDM: Please indicate if diastolic blood pressure is considered NCS or CS and report AE if applicable. Thank you' answered with 'not clinically significant' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 20:43:14
User opened query 'Per CDM: Please indicate if diastolic blood pressure is considered NCS or CS and report AE if applicable. Thank you' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 20:05:19
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	15 Oct 2020 20:04:07
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 21:18:31
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		13 Oct 2020 21:18:20
User entered '54'	(b) (4), (b) (6)	13 Oct 2020 21:18:20

US3362083

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:55
User entered 'mmHg'	System	13 Oct 2020 21:18:20

US3362083

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:55

US3362083

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:55

US3362083

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:18:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 21:18:44

US3362083

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4)	18 Nov 2020 21:18:03
User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 20:42:26
User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	02 Nov 2020 20:40:54
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 21:18:44

US3362083

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:35:02

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:18:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 21:19:17

US3362083

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:35:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:55
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 28 SEP 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in the Illness Visit Day 1 in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 08:20:08
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:18:16
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 28 SEP 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in the Illness Visit Day 1 in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'illness visit D1 was 31AUG2020 and illness visit D28 was 28SEP2020. will complete a data change request form for PPD' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	11 Nov 2020 14:23:04
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 28 SEP 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in the Illness Visit Day 1 in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 05:39:24
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 21:19:17

US3362083

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

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:42:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 21:26:31

US3362083

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

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:42:55
User entered '06 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 21:26:31

US3362083

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

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:42:55
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	06 Jan 2021 21:26:31

US3362083

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

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'UNBLND_DECIDE'	System	06 Jan 2021 21:26:31

US3362083

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:02

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:43:22
User entered '06 Jan 2021' reason for change: Data Entry Error	Amy Thomassie (b) (4)	18 Feb 2021 21:08:50
User entered '24 Dec 2020'	(b) (4), (b) (6)	06 Jan 2021 21:27:47

US3362083

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:02

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:58:12

US3362083

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:02

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:43:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 21:27:47

US3362083

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:02

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:43:22
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 00:28:31
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 15:44:28
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 15:44:20
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 13:23:20
User entered 'AMENDMENT 5 (AMENDMENT 5)'	System	10 Mar 2021 16:55:28
WR# 5295537		
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:58:12

US3362083

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:02

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:43:22
User closed query 'Per CDM: Please clarify the reason why updated informed consent was signed much earlier than actual visit and unblinding took place. Thank you! ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 17:13:01
Query 'Per CDM: Please clarify the reason why updated informed consent was signed much earlier than actual visit and unblinding took place. Thank you! ' answered with 'updated ICF date' (Site from DM).	Amy Thomassie (b) (4)	18 Feb 2021 21:08:53
User opened query 'Per CDM: Please clarify the reason why updated informed consent was signed much earlier than actual visit and unblinding took place. Thank you! ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 10:42:08
Reviewed for Data Management.	(b) (4), (b) (6)	18 Feb 2021 10:42:00
User entered '06 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 21:27:47

US3362083

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:02

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:43:22
User closed query 'Per IRT this subject was randomized to placebo treatment assignment. Please review and reconcile.' (Site from DM).		09 Apr 2021 21:21:12
Query 'Per IRT this subject was randomized to placebo treatment assignment. Please review and reconcile.' answered with 'updated ' (Site from DM).		08 Apr 2021 15:44:30
User entered 'Placebo (Placebo)' reason for change: Data Entry Error		08 Apr 2021 15:44:20
User opened query 'Per IRT this subject was randomized to placebo treatment assignment. Please review and reconcile.' (Site from DM).		08 Apr 2021 09:59:18
User entered 'mRNA-1273 (mRNA-1273)'		06 Jan 2021 21:27:47

US3362083

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:02

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	12 Apr 2021 14:43:22
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 06:45:41
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	06 Jan 2021 21:27:47

US3362083

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:02

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	12 Apr 2021 14:43:22
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 06:45:41
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	06 Jan 2021 21:27:47

US3362083

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:02

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:43:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 21:27:47

US3362083

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:02

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'I'	System	06 Jan 2021 21:27:47

US3362083

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:02

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'I'	System	06 Jan 2021 21:27:47

US3362083

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:45:54
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:45:54
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:02

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered empty.	System	06 Jan 2021 21:33:55
DataPoint set to visible.	System	06 Jan 2021 21:27:47

US3362083

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:45:54
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:45:54
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:02

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered empty.	System	06 Jan 2021 21:33:55
DataPoint set to visible.	System	06 Jan 2021 21:27:47

US3362083

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:45:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:45:54
User entered '06 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:45:54
User entered '08:35'	(b) (4), (b) (6)	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered '06 Jan 2021 08:35'	System	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:45:54
User entered '36.6' C	(b) (4), (b) (6)	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:45:54
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:45:54
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:45:54
User entered '62'	(b) (4), (b) (6)	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'bpm'	System	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:45:54
User entered '18'	(b) (4), (b) (6)	06 Jan 2021 21:33:55

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'breaths/min'	System	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:45:54
User entered '103'	(b) (4), (b) (6)	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'mmHg'	System	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:45:54
User entered '66'	(b) (4), (b) (6)	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'mmHg'	System	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:45:54
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:45:54
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:02

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered empty.	System	06 Jan 2021 21:33:55
DataPoint set to visible.	System	06 Jan 2021 21:27:47

US3362083

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:45:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:45:54
User entered '06 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:45:54
User entered '09:26'	(b) (4), (b) (6)	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered '06 Jan 2021 09:26'	System	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:45:54
User entered '36.7' C	(b) (4), (b) (6)	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:45:54
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:45:54
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:45:54
User entered '70'	(b) (4), (b) (6)	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'bpm'	System	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:45:54
User entered '18'	(b) (4), (b) (6)	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'breaths/min'	System	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:45:54
User entered '100'	(b) (4), (b) (6)	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'mmHg'	System	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:45:54
User entered '65'	(b) (4), (b) (6)	06 Jan 2021 21:33:55

US3362083

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'mmHg'	System	06 Jan 2021 21:33:55

US3362083

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:46:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 21:34:09

US3362083

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:46:09
User entered '06 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 21:34:09

US3362083

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:47:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 21:34:44

US3362083

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:47:27
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 21:34:44

US3362083

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:47:27
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 21:34:44

US3362083

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'mRNA-1273'	System	06 Jan 2021 21:34:44
DataPoint set to visible.	System	06 Jan 2021 21:27:47

US3362083

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:47:27
User entered '06 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 21:34:44

US3362083

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:47:27
User entered '08:51'	(b) (4), (b) (6)	06 Jan 2021 21:34:44

US3362083

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered '06 Jan 2021 08:51'	System	06 Jan 2021 21:34:44

US3362083

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:47:27
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	06 Jan 2021 21:34:44

US3362083

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:47:27
User entered 'ONCE'	System	06 Jan 2021 21:34:44

US3362083

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'INTRAMUSCULAR'	System	06 Jan 2021 21:34:44

US3362083

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:48:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 21:35:51

US3362083

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:48:23
User entered '06 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 21:35:51

US3362083

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:48:23
User entered '08:13'	(b) (4), (b) (6)	06 Jan 2021 21:35:51

US3362083

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered '06 Jan 2021 08:13'	System	06 Jan 2021 21:35:51

US3362083

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:35:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:49:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 21:36:18

US3362083

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:35:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:49:41
User entered '06 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 21:36:18

US3362083

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:35:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:49:41
User entered '08:19'	(b) (4), (b) (6)	06 Jan 2021 21:36:18

US3362083

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:35:02

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered '06 Jan 2021 08:19'	System	06 Jan 2021 21:36:18

US3362083

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

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:50:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 21:36:28

US3362083

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

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'I'	System	06 Jan 2021 21:36:28

US3362083

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:50:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 23:12:15

US3362083

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:50:52
User entered '13 Jan 2021'	(b) (4), (b) (6)	13 Jan 2021 23:12:15

US3362083

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:50:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	13 Jan 2021 23:12:15

US3362083

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:50:52
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 23:12:15

US3362083

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:50:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 23:12:21

US3362083

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'I'	System	13 Jan 2021 23:12:21

US3362083

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered '1'	System	13 Jan 2021 23:12:21
DataPoint set to visible.	System	13 Jan 2021 23:12:21

US3362083

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 16:06:25

US3362083

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '5 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:06:25

US3362083

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:06:25

US3362083

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'OLD29'	System	05 Feb 2021 16:06:25

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '5 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '07:44'	(b) (4), (b) (6)	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered '5 Feb 2021 07:44'	System	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '36.8' C	(b) (4), (b) (6)	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '53'	(b) (4), (b) (6)	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'bpm'	System	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '16'	(b) (4), (b) (6)	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'breaths/min'	System	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '102'	(b) (4), (b) (6)	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'mmHg'	System	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '73'	(b) (4), (b) (6)	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'mmHg'	System	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '5 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '08:45'	(b) (4), (b) (6)	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered '5 Feb 2021 08:45'	System	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '36.4' C	(b) (4), (b) (6)	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '58'	(b) (4), (b) (6)	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'bpm'	System	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '18'	(b) (4), (b) (6)	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'breaths/min'	System	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '101'	(b) (4), (b) (6)	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'mmHg'	System	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	08 Feb 2021 18:22:54
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	05 Feb 2021 16:08:24
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		05 Feb 2021 16:02:52
User entered '54'	(b) (4), (b) (6)	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'mmHg'	System	05 Feb 2021 16:02:52

US3362083

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 16:06:37

US3362083

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:02

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 16:06:37

US3362083

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:07:22

US3362083

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 16:07:22

US3362083

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:07:22

US3362083

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'mRNA-1273'	System	05 Feb 2021 16:07:22
DataPoint set to visible.	System	13 Jan 2021 23:12:21

US3362083

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '5 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:07:22

US3362083

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '08:08'	(b) (4), (b) (6)	05 Feb 2021 16:07:22

US3362083

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered '5 Feb 2021 08:08'	System	05 Feb 2021 16:07:22

US3362083

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:07:22

US3362083

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'ONCE'	System	05 Feb 2021 16:07:22

US3362083

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'INTRAMUSCULAR'	System	05 Feb 2021 16:07:22

US3362083

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 16:07:34

US3362083

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'I'	System	05 Feb 2021 16:07:34

US3362083

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:50

US3362083

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:50

US3362083

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:50

US3362083

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:50

US3362083

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:58

US3362083

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'I'	System	12 Feb 2021 19:33:58

US3362083

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	03 Mar 2021 14:37:52

US3362083

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '3 Mar 2021'	Alexandra Caillouet (b) (4)	03 Mar 2021 14:37:52

US3362083

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Clinic (Clinic)'	Alexandra Caillouet (b) (4)	03 Mar 2021 14:37:52

US3362083

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'OLD57'	System	03 Mar 2021 14:37:52

US3362083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	03 Mar 2021 14:38:52

US3362083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '3 Mar 2021'	Alexandra Caillouet (b) (4)	03 Mar 2021 14:38:52

US3362083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '07:42'	Alexandra Caillouet (b) (4)	03 Mar 2021 14:38:52

US3362083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered '3 Mar 2021 07:42'	System	03 Mar 2021 14:38:52

US3362083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '36.7' C	Alexandra Caillouet (b) (4)	03 Mar 2021 14:38:52

US3362083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Oral (Oral)'	Alexandra Caillouet (b) (4)	03 Mar 2021 14:38:52

US3362083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered empty.	Alexandra Caillouet (b) (4)	03 Mar 2021 14:38:52

US3362083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '58'	Alexandra Caillouet (b) (4)	03 Mar 2021 14:38:52

US3362083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'bpm'	System	03 Mar 2021 14:38:52

US3362083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '18'	Alexandra Caillouet (b) (4)	03 Mar 2021 14:38:52

US3362083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'breaths/min'	System	03 Mar 2021 14:38:52

US3362083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '103'	Alexandra Caillouet (b) (4)	03 Mar 2021 14:38:52

US3362083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'mmHg'	System	03 Mar 2021 14:38:52

US3362083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '64'	Alexandra Caillouet (b) (4)	03 Mar 2021 14:38:52

US3362083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered 'mmHg'	System	03 Mar 2021 14:38:52

US3362083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23

US3362083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23

US3362083

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'No (N)'	Alexandra Caillouet (b) (4)	03 Mar 2021 14:39:02

US3362083

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:02

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered empty.	Alexandra Caillouet (b) (4)	03 Mar 2021 14:39:02

US3362083

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	03 Mar 2021 14:39:41

US3362083

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '3 Mar 2021'	Alexandra Caillouet (b) (4)	03 Mar 2021 14:39:41

US3362083

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:02

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
User entered '07:45'	Alexandra Caillouet (b) (4)	03 Mar 2021 14:39:41

US3362083

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:44:23
User entered '3 Mar 2021 07:45'	System	03 Mar 2021 14:39:41

US3362083

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:35:02

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:24:35
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	04 Nov 2020 19:51:24
User entered 'Yes (Y)' reason for change: New Information		01 Sep 2020 16:12:31
User entered 'No (N)'		26 Aug 2020 16:43:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:07:22
User entered	System	07 Sep 2020 21:06:53
'USA-US112-2020-mRNA-1273-P301000003'		
User entered 'New'	(b) (4), (b) (6)	07 Sep 2020 21:06:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:52:39
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
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)	25 Nov 2020 01:01:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Nov 2020 01:01:03
Data point term sent to Coder	System	25 Nov 2020 01:00:19
Datapoint queued for coding (5166075).	System	25 Nov 2020 00:59:18
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 17:33:33
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).	Crystal Rowell (b) (4)	23 Nov 2020 17:33:33
Coding entries removed.	Crystal Rowell (b) (4)	23 Nov 2020 17:33:26
User entered 'COVID-19' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Nov 2020 17:33:26
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 12:23:55
User closed query 'PV Query: Please update event term to 'COVID-19'. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:12:51
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)	19 Nov 2020 21:45:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	19 Nov 2020 21:45:56
User: Coder System - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	System	19 Nov 2020 21:45:31
Query 'PV Query: Please update event term to	(b) (4), (b) (6)	19 Nov 2020 21:45:04
'COVID-19'. ' answered with 'updated query, the		
ICD-10 code for "Covid-like Illness" is U07.2.' (Site		
from Safety).		
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 21:44:58
Coding entries removed.		19 Nov 2020 21:44:58
User entered 'Symptomatic Covid-19' reason for		19 Nov 2020 21:44:58
change: Data Entry Error		
User opened query 'PV Query: Please update event		19 Nov 2020 21:31:52
term to 'COVID-19'. ' (Site from Safety).		
User coded data point as SOC: Investigations,	Coder Import (b) (4)	10 Nov 2020 23:21:43
HLGT: Microbiology and serology investigations,	(b) (4)	
HLT: Virus identification and serology, PT:		
SARS-CoV-2 test positive, LLT: SARS-CoV-2 test		
positive - version MedDRA\23.0.		
User coded data point as Term Coded data point by	Coder Import (b) (4)	10 Nov 2020 23:21:43
User: (b) (6) - version MedDRA\23.0.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User closed query 'Per CDM: Please advise if this is	(b) (4), (b) (6)	16 Oct 2020 09:01:30
Symptomatic. If Symptomatic, please add to term.'		
(Site from DM).		
Query 'Per CDM: Please advise if this is	(b) (4), (b) (6)	15 Oct 2020 19:53:40
Symptomatic. If Symptomatic, please add to term.'		
answered with 'SYMPTOMS WERE LISTED IN AE		
EVEN SUMMARY LOG FEVER,MUSCLE		
ACHES' (Site from DM).		
User opened query 'Per CDM: Please advise if this is	(b) (4), (b) (6)	11 Oct 2020 14:48:50
Symptomatic. If Symptomatic, please add to term.'		
(Site from DM).		
User coded data point as SOC: Investigations,	Coder Import (b) (4)	05 Sep 2020 17:12:34
HLGT: Microbiology and serology investigations,	(b) (4)	
HLT: Virus identification and serology, PT:		
SARS-CoV-2 test positive, LLT: SARS-CoV-2 test		
positive - version MedDRA\23.0.		
User coded data point as Term Coded data point by	Coder Import (b) (4)	05 Sep 2020 17:12:34
User: (b) (6) - version MedDRA\23.0.	(b) (4)	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	05 Sep 2020 15:47:43
User entered 'SARS COV 2 positive'	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User closed query 'PV Query: Please confirm if the COVID-19 test was drawn and/or resulted on 31 Aug 2020. If not, please clarify the dates. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 11:42:19
User closed query 'PV query: Event start date was listed as 28 August, however positive test and first symptoms were reported with a date of 31 Aug 2020. Please clarify. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 11:42:14
Query 'PV Query: Please confirm if the COVID-19 test was drawn and/or resulted on 31 Aug 2020. If not, please clarify the dates. ' answered with 'start date of symptoms is confirmed as correct ' (Site from Safety).	Amy Thomassie (b) (4)	19 Sep 2020 16:09:33
	(b) (4)	
Query 'PV query: Event start date was listed as 28 August, however positive test and first symptoms were reported with a date of 31 Aug 2020. Please clarify. ' answered with 'confirmed as correct' (Site from Safety).	Amy Thomassie (b) (4)	19 Sep 2020 16:08:44
	(b) (4)	
User opened query 'PV Query: Please confirm if the COVID-19 test was drawn and/or resulted on 31 Aug 2020. If not, please clarify the dates. ' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 14:19:00
User opened query 'PV query: Event start date was listed as 28 August, however positive test and first symptoms were reported with a date of 31 Aug 2020. Please clarify. ' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 14:18:02
User entered '28 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 23:15:45
User entered '5 Sep 2020'	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 15:47:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	08 Sep 2020 23:15:45
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User closed query 'PV Query: According to the symptom log, the subject was not free of symptoms on 31Aug2020 (currently reported as end date). Please update the end date to the date of resolution of symptoms. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 11:42:27
Query 'PV Query: According to the symptom log, the subject was not free of symptoms on 31Aug2020 (currently reported as end date). Please update the end date to the date of resolution of symptoms. ' answered with 'updated ' (Site from Safety).	Amy Thomassie (b) (4)	19 Sep 2020 16:07:56
	(b) (4)	
User entered '06 Sep 2020' reason for change: New Information	Amy Thomassie (b) (4)	19 Sep 2020 16:07:27
	(b) (4)	
User opened query 'PV Query: According to the symptom log, the subject was not free of symptoms on 31Aug2020 (currently reported as end date). Please update the end date to the date of resolution of symptoms. ' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 14:17:45
User entered '31 Aug 2020' reason for change: New Information	(b) (4), (b) (6)	08 Sep 2020 23:15:45
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 15:47:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 23:15:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 23:15:45
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 23:15:45
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 15:47:03
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 23:16:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 23:16:08
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	08 Sep 2020 23:16:08
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 15:47:03
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:25:11
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	19 Sep 2020 16:07:27
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 00:47:11
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	08 Sep 2020 23:17:45
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 23:16:46
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 23:15:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 23:15:45
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 23:15:45
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	07 Sep 2020 21:01:58
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 15:47:03
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 23:16:46
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 23:15:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 23:15:45
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 23:15:45
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 15:47:03
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 15:03:43
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 'please clarify, IP discontinued due to being COVID + per protocol ' (Site from System).	Crystal Rowell (b) (4)	08 Oct 2020 18:50:30
	(b) (4)	
Query 'Per CDM re-query: Thank you for your answer. However, subject withdrawn from treatment. Please consider updating "Dosing discontinuation" form under End of study folder. Thank you!' canceled (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 13:16:07
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	07 Oct 2020 20:43:12
User opened query 'Per CDM re-query: Thank you for your answer. However, subject withdrawn from treatment. Please consider updating "Dosing discontinuation" form under End of study folder. Thank you!' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 06:04:56
User closed query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 06:04:56
Query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' answered with 'Subject not withdrawn from the study. IP not given. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 20:09:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 11:57:35
User closed query 'PV query: Event start date was listed as 28 August, however positive test and first symptoms were reported with a date of 31 Aug 2020. Please clarify. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 11:42:35
Query 'PV query: Event start date was listed as 28 August, however positive test and first symptoms were reported with a date of 31 Aug 2020. Please clarify. ' answered with 'start date is confirmed as 28AUG' (Site from Safety).	Amy Thomassie (b) (4)	19 Sep 2020 16:10:15
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Amy Thomassie (b) (4)	19 Sep 2020 16:07:27
User opened query 'PV query: Event start date was listed as 28 August, however positive test and first symptoms were reported with a date of 31 Aug 2020. Please clarify. ' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 14:18:28
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 23:17:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 23:17:26
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 23:17:26
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 15:47:03
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

None

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	15 Oct 2020 19:48:42
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 19:48:42
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	15 Oct 2020 19:47:21
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 19:47:21
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:26:05
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 20:09:14
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 20:08:48
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 02:11:00
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	08 Sep 2020 23:17:03
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 23:17:03
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Sep 2020 15:47:03
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 20:08:48
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 23:17:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 23:17:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	08 Sep 2020 23:17:17
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 15:47:03
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:53:17
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:11:36
User closed query 'PV Query: Thank you for your response. However, the symptoms provided for day 1 are for 31 August 2020. Please specify the symptoms the subject experienced on 28 Aug 2020, Also, please specify the type of SARS CoV2 test the subject underwent that day.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 13:56:21
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:53:17
Query 'PV Query: Thank you for your response. However, the symptoms provided for day 1 are for 31 August 2020. Please specify the symptoms the subject experienced on 28 Aug 2020, Also, please specify the type of SARS CoV2 test the subject underwent that day.' answered with 'subject called clinic and seen same day 31Aug2020- subject developed symptoms over the weekend when we were out of the office, please clarify what you are asking- we have completed edc per guidelines and visits per protocol ' (Site from Safety).	Crystal Rowell (b) (4) (b) (4)	04 Nov 2020 16:04:06
User opened query 'PV Query: Thank you for your response. However, the symptoms provided for day 1 are for 31 August 2020. Please specify the symptoms the subject experienced on 28 Aug 2020, Also, please specify the type of SARS CoV2 test the subject underwent that day.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 18:56:01
User closed query 'PV Query: Please provide the dates that the results of SAR CoV 2 tests performed on 28 Aug 2020 and 31 Aug 2020 were available.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 23:46:10
User closed query 'PV Query: Please specify the symptoms the subject experienced on 28 Aug 2020, Also, please specify the type of SARS CoV2 test the subject underwent that day.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 23:45:52
Query 'PV Query: Please provide the dates that the results of SAR CoV 2 tests performed on 28 Aug 2020 and 31 Aug 2020 were available.' answered with 'updated date of onsite clinic illness visit' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 16:37:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please specify the symptoms the subject experienced on 28 Aug 2020, Also, please specify the type of SARS CoV2 test the subject underwent that day.' answered with 'please see symptoms on illness visit day 1' (Site from Safety). User entered 'CONVALESCENT VISIT 31AUG2020 FOR STUDY SWAB COLLECTION THAT WAS CONFIRMED AS POSITIVE on 04sep2020. NO REPORT OF EXPOSURE.' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 16:37:47
User opened query 'PV Query: Please provide the dates that the results of SAR CoV 2 tests performed on 28 Aug 2020 and 31 Aug 2020 were available.' (Site from Safety).		28 Oct 2020 16:37:29
User opened query 'PV Query: Please specify the symptoms the subject experienced on 28 Aug 2020, Also, please specify the type of SARS CoV2 test the subject underwent that day.' (Site from Safety).		22 Oct 2020 19:53:47
User closed query 'PV Query: Did the subject have any known exposure to COVID-19 or risk factors for the event?' (Site from Safety).		22 Oct 2020 19:53:39
Query 'PV Query: Did the subject have any known exposure to COVID-19 or risk factors for the event?' answered with 'no report of exposure' (Site from Safety).		21 Sep 2020 11:42:40
User entered 'symptom onset 28AUG2020. tested positive for COVID 19 at local urgent care facility. convalescent visit 31AUG2020 for study swab collection that was confirmed as positive. no report of exposure' reason for change: Data Entry Error	Amy Thomassie (b) (4)	19 Sep 2020 16:13:01
User opened query 'PV Query: Did the subject have any known exposure to COVID-19 or risk factors for the event?' (Site from Safety).	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	19 Sep 2020 16:12:50
	(b) (4)	
User opened query 'PV Query: Did the subject have any known exposure to COVID-19 or risk factors for the event?' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 14:18:42
	Amy Thomassie (b) (4)	05 Sep 2020 15:47:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Sep 2020 23:16:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:02

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 15:47:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:24:35
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
User closed query 'Per CDM: "Were any prior/concomitant medication and vaccinations taken" is recorded as "Yes" however, Prior/concomitant medications and/or vaccinations page is 'inactivated'. Please review and update to support corresponding AE data' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 11:35:31
Query 'Per CDM: "Were any prior/concomitant medication and vaccinations taken" is recorded as "Yes" however, Prior/concomitant medications and/or vaccinations page is 'inactivated'. Please review and update to support corresponding AE data' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 17:08:39
User opened query 'Per CDM: "Were any prior/concomitant medication and vaccinations taken" is recorded as "Yes" however, Prior/concomitant medications and/or vaccinations page is 'inactivated'. Please review and update to support corresponding AE data' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 04:36:32
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:48:55
User entered 'Yes (Y)' reason for change: Data Entry Error		01 Sep 2020 16:17:39
User entered 'No (N)'		08 Aug 2020 15:51:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:02

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
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)	03 Dec 2020 23:06:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Dec 2020 23:06:48
Data point term sent to Coder Coding entries removed.	System Alexandra Caillouet	03 Dec 2020 23:05:40 03 Dec 2020 23:05:36
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)	05 Nov 2020 17:08:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 17:08:22
Data point term sent to Coder	System	05 Nov 2020 17:07:16
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 17:06:30
Data point term sent to Coder	System	04 Nov 2020 20:11:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
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)	01 Sep 2020 16:20:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 16:20:42
Data point term sent to Coder	System	01 Sep 2020 16:20:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:02

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'tylenol'	(b) (4), (b) (6)	01 Sep 2020 16:19:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the AE CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable.'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 05:05:23
(Site from DM).		
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the AE CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable.'	(b) (4), (b) (6)	10 Nov 2020 16:22:28
' answered with 'updated' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 16:22:22
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the AE CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable.'	(b) (4), (b) (6)	06 Nov 2020 10:51:17
(Site from DM).		
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 16:19:12

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
User closed query 'Per DM CLR: Please note that this condition is not present in either AE and eDiary. Review indication and ensure that there is a corresponding condition recorded in the most applicable eCRF. Update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 05:02:01
Query 'Per DM CLR: Please note that this condition is not present in either AE and eDiary. Review indication and ensure that there is a corresponding condition recorded in the most applicable eCRF. Update as appropriate. Otherwise, provide clarification. ' answered with 'Updated to corresponding condition.' (Site from DM).	Alexandra Caillouet (b) (4)	03 Dec 2020 23:05:54
User entered 'COVID-19' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	03 Dec 2020 23:05:36
User opened query 'Per DM CLR: Please note that this condition is not present in either AE and eDiary. Review indication and ensure that there is a corresponding condition recorded in the most applicable eCRF. Update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 21:25:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 16:57:20

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:02

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:01:21
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.'	(b) (4), (b) (6)	23 Oct 2020 06:16:46
' (Site from DM).		
User entered 'fever'	(b) (4), (b) (6)	01 Sep 2020 16:19:12

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered '500'	(b) (4), (b) (6)	01 Sep 2020 16:19:12

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Sep 2020 16:19:12

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 16:19:12

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered 'as needed (PRN)'	(b) (4), (b) (6)	01 Sep 2020 16:19:12

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 16:19:12

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Sep 2020 16:19:12

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 16:19:12

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered '29 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 16:19:12

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 16:19:12

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered 'No (N)' reason for change: Data Entry Error		28 Oct 2020 16:01:12
User entered 'Yes (Y)'		01 Sep 2020 16:19:12

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered '31 Aug 2020' reason for change: Data Entry Error		28 Oct 2020 16:01:12
User entered empty.		01 Sep 2020 16:19:12

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 16:19:12

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered empty.	System	01 Sep 2020 16:19:12

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered empty.	System	01 Sep 2020 16:19:12

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered empty.	System	01 Sep 2020 16:19:12

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 08:11:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 08:11:10
Data point term sent to Coder	System	03 Dec 2020 23:06:40
Coding entries removed.	Alexandra Caillouet	03 Dec 2020 23:06:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 17:08:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 17:08:21
Data point term sent to Coder	System	05 Nov 2020 17:07:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 17:06:30
Data point term sent to Coder	System	04 Nov 2020 20:11:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 03:40:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 03:40:38
Data point term sent to Coder	System	01 Sep 2020 16:22:15
User entered 'zinc'	(b) (4), (b) (6)	01 Sep 2020 16:21:25

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the AE CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 05:06:19
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the AE CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 16:22:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 16:22:40
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the AE CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:51:30
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.		04 Nov 2020 20:11:18
User entered 'Yes (Y)'		01 Sep 2020 16:21:25

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
User closed query 'Per DM CLR: Please confirm if this is related to AE#1 COVID-19 (28AUG2020). If not, please note that this condition is not present in either AE and eDiary. Review indication and ensure that there is a corresponding condition recorded in the most applicable eCRF. Update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 05:02:37
Query 'Per DM CLR: Please confirm if this is related to AE#1 COVID-19 (28AUG2020). If not, please note that this condition is not present in either AE and eDiary. Review indication and ensure that there is a corresponding condition recorded in the most applicable eCRF. Update as appropriate. Otherwise, provide clarification. ' answered with 'Updated to corresponding condition.' (Site from DM).	Alexandra Caillouet (b) (4)	03 Dec 2020 23:06:34
User entered 'COVID-19' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	03 Dec 2020 23:06:22
User opened query 'Per DM CLR: Please confirm if this is related to AE#1 COVID-19 (28AUG2020). If not, please note that this condition is not present in either AE and eDiary. Review indication and ensure that there is a corresponding condition recorded in the most applicable eCRF. Update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 21:27:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.		04 Nov 2020 20:11:18
User entered 'fever/covid positive'		01 Sep 2020 16:21:25

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered '45'		01 Sep 2020 16:21:25

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered 'mg (mg)'		01 Sep 2020 16:21:25

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered empty.		01 Sep 2020 16:21:25

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered 'once daily (QD)'		01 Sep 2020 16:21:25

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered empty.		01 Sep 2020 16:21:25

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered 'Oral (ORAL)'		01 Sep 2020 16:21:25

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered empty.		01 Sep 2020 16:21:25

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.		04 Nov 2020 20:11:18
User entered '29 Aug 2020'		01 Sep 2020 16:21:25

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered '0'		01 Sep 2020 16:21:25

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 11:23:30
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Crystal Rowell (b) (4) (b) (4)	18 Nov 2020 21:46:23
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	18 Nov 2020 21:46:16
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 00:50:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 16:21:25

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
User entered '05 Sep 2020' reason for change: Data Entry Error	(b) (4)	
User entered '05 Sep 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	18 Nov 2020 21:46:16
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 16:21:25

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:20
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 16:21:25

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:08
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered '1'	System	01 Sep 2020 16:21:25

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:08
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered '1'	System	01 Sep 2020 16:21:25

US3362083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:08
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 17:06:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 20:11:18
User entered '804 (804)'	System	01 Sep 2020 16:21:25

US3362083

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:35:02

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:53:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:49:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Aug 2020 15:51:39

US3362083

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:35:02

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:54:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User closed query 'Per CDM: Date of dosing discontinuation is recorded as '31 AUG 2020' but end date of corresponding Adverse event on AE form is recorded as 6 SEP 2020.Kindly verify and update data accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 13:17:45
Query 'Per CDM: Date of dosing discontinuation is recorded as '31 AUG 2020' but end date of corresponding Adverse event on AE form is recorded as 6 SEP 2020.Kindly verify and update data accordingly.' answered with 'medicine discontinued prior to AE resolving ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:57:55
User opened query 'Per CDM: Date of dosing discontinuation is recorded as '31 AUG 2020' but end date of corresponding Adverse event on AE form is recorded as 6 SEP 2020.Kindly verify and update data accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 04:32:10
User closed query "Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2', However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 16:44:49
Query "Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2', However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 20:41:36
User opened query "Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2', However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 06:59:16

US3362083

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:35:02

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM-Date of dosing discontinuation is recorded as '5 SEP 2020' but end date of corresponding Adverse event on Ae form is recorded as 6 sep 2020.Kindly verify and update data accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 06:50:20
Query 'Per CDM-Date of dosing discontinuation is recorded as '5 SEP 2020' but end date of corresponding Adverse event on Ae form is recorded as 6 sep 2020.Kindly verify and update data accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 20:46:37
User entered '31 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 20:46:29
User opened query 'Per CDM-Date of dosing discontinuation is recorded as '5 SEP 2020' but end date of corresponding Adverse event on Ae form is recorded as 6 sep 2020.Kindly verify and update data accordingly. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 08:00:35
User entered '5 Sep 2020'	(b) (4), (b) (6)	07 Oct 2020 20:43:12

US3362083

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:35:02

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:54:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User closed query 'Per CDM: Primary reason for dosing discontinuation is recoded as 'AE (specify)' and other as 'SARS COV 2 POSITIVE'. However 'SARS COV 2 POSITIVE' can be selected as primary reason for discontinuation as per CCG's. Please verify and update.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 11:33:20
Query 'Per CDM: Primary reason for dosing discontinuation is recoded as 'AE (specify)' and other as 'SARS COV 2 POSITIVE'. However 'SARS COV 2 POSITIVE' can be selected as primary reason for discontinuation as per CCG's. Please verify and update.' answered with 'updated per query ' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	11 Nov 2020 14:07:09
User entered 'Due to SARS-COV-2 (COVID)' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	11 Nov 2020 14:05:50
User opened query 'Per CDM: Primary reason for dosing discontinuation is recoded as 'AE (specify)' and other as 'SARS COV 2 POSITIVE'. However 'SARS COV 2 POSITIVE' can be selected as primary reason for discontinuation as per CCG's. Please verify and update.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 13:24:06
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	02 Nov 2020 21:42:08
User closed query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2',However, confirm that corresponding data is recorded on 'Covid -19 Assessment' form ,` and 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 06:49:45

US3362083

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:35:02

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2',However, confirm that corresponding data is recorded on 'Covid -19 Assessment' form ,` and 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' answered with 'subject is still in study; did not get second injection; ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 20:47:21
User opened query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2',However, confirm that corresponding data is recorded on 'Covid -19 Assessment' form ,` and 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 07:59:09
User entered 'Due to SARS-COV-2 (COVID)'	(b) (4), (b) (6)	07 Oct 2020 20:43:12

US3362083

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:54:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	11 Nov 2020 14:05:50
User closed query 'Per CDM: "other specify' is entered as "SARS COV 2 Positive", however "Primary reason for dosing discontinuation is not "Due to SARS-COV-2". Please review and consider updating or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 13:22:09
Query 'Per CDM: "other specify' is entered as "SARS COV 2 Positive", however "Primary reason for dosing discontinuation is not "Due to SARS-COV-2". Please review and consider updating or comment accordingly. ' answered with 'primary reason for IP dosing discontinuation is due to SARs COV 2 positive test' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 21:01:40
User opened query 'Per CDM: "other specify' is entered as "SARS COV 2 Positive", however "Primary reason for dosing discontinuation is not "Due to SARS-COV-2". Please review and consider updating or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 16:44:49
User entered 'SARS Cov 2 positive' reason for change: Data Entry Error	Crystal Rowell (b) (4)	02 Nov 2020 21:42:08
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:43:12

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:35:02

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:54:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Nov 2020 16:45:43
Query 'Data is required. Please complete.' answered with 'data entry error; subject is still in study' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 20:42:49
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 20:42:26
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 20:42:26
User entered '31 Aug 2020'	(b) (4), (b) (6)	02 Nov 2020 20:40:54

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:35:02

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:54:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'data entry error; subject is still in study' (Site from System).	(b) (4), (b) (6)	03 Nov 2020 16:45:44
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 20:42:51
User entered empty; reason for change Data Entry Error	System	02 Nov 2020 20:42:26
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4), (b) (6)	02 Nov 2020 20:42:26
	(b) (4), (b) (6)	02 Nov 2020 20:40:54

US3362083

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:35:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:54:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 20:42:26
User entered 'SARS-COV 2 positive'	(b) (4), (b) (6)	02 Nov 2020 20:40:54

US3362083

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:35:02

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:54:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:40:54

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:35:02

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:54:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:40:54

US3362083

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:35:02

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:54:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:40:54

US3362083

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:35:02

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:54:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:10:14
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:40:54

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered		
'USA-US112-2020-MRNA-1273-P301000003'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered 'Jordan'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered 'Whatley'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered '5326 O'donovan dr'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered 'baton rouge'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 13:56:32
Un-reviewed for Safety.	System	29 Oct 2020 23:46:39
User entered empty.	System	29 Oct 2020 23:46:39
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 23:46:26
User entered 'LA'	(b) (4), (b) (6)	15 Oct 2020 19:52:34

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered '70808'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:33:50
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 00:47:30
User entered 'US' (non-conformant).	System	07 Sep 2020 21:09:25

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	20 Nov 2020 15:13:34
User entered '5'	System	05 Nov 2020 13:56:41
User entered '4'	System	29 Oct 2020 23:46:39
User entered '3'	System	21 Sep 2020 11:43:02
User entered '2'	System	10 Sep 2020 00:47:45
User entered '1'	System	07 Sep 2020 21:09:25

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered		
'USA-US112-2020-MRNA-1273-P301000003'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered 'Jordan'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered 'Whatley'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered '5326 O'donovan dr'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered 'baton rouge'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 13:56:32
Un-reviewed for Safety.	System	29 Oct 2020 23:46:39
User entered empty.	System	29 Oct 2020 23:46:39
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 23:46:26
User entered 'LA'	(b) (4), (b) (6)	15 Oct 2020 19:52:34

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered '70808'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:33:50
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 00:47:30
User entered 'US' (non-conformant).	System	07 Sep 2020 21:09:25

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	20 Nov 2020 15:13:34
User entered '5'	System	05 Nov 2020 13:56:41
User entered '4'	System	29 Oct 2020 23:46:39
User entered '3'	System	21 Sep 2020 11:43:02
User entered '2'	System	10 Sep 2020 00:47:45
User entered '1'	System	07 Sep 2020 21:09:25

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:35:02

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:26:45
User entered '07/Sep/2020 17:09'	System	07 Sep 2020 21:09:25

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:35:02

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.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.		10 Sep 2020 00:47:30
User entered 'I'		07 Sep 2020 21:09:25

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered		
'USA-US112-2020-MRNA-1273-P301000003'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered 'Jordan'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered 'Whatley'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered '5326 O'donovan dr'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered 'baton rouge'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 13:56:32
Un-reviewed for Safety.	System	29 Oct 2020 23:46:39
User entered empty.	System	29 Oct 2020 23:46:39
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 23:46:26
User entered 'LA'	(b) (4), (b) (6)	15 Oct 2020 19:52:34

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered '70808'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:26:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:33:50
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 00:47:30
User entered 'US' (non-conformant).	System	07 Sep 2020 21:09:25

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	20 Nov 2020 15:13:34
User entered '5'	System	05 Nov 2020 13:56:41
User entered '4'	System	29 Oct 2020 23:46:39
User entered '3'	System	21 Sep 2020 11:43:02
User entered '2'	System	10 Sep 2020 00:47:45
User entered '1'	System	07 Sep 2020 21:09:25

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:35:02

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:26:45
User entered '09/Sep/2020 20:47'	System	10 Sep 2020 00:47:45

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:35:02

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.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4) (u) (+), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.		21 Sep 2020 11:42:51
User entered '1'		10 Sep 2020 00:47:45

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered		
'USA-US112-2020-MRNA-1273-P301000003'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered 'Jordan'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered 'Whatley'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered '5326 O'donovan dr'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered 'baton rouge'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 13:56:32
Un-reviewed for Safety.	System	29 Oct 2020 23:46:39
User entered empty.	System	29 Oct 2020 23:46:39
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 23:46:26
User entered 'LA'	(b) (4), (b) (6)	15 Oct 2020 19:52:34

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered '70808'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:33:50
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 00:47:30
User entered 'US' (non-conformant).	System	07 Sep 2020 21:09:25

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	20 Nov 2020 15:13:34
User entered '5'	System	05 Nov 2020 13:56:41
User entered '4'	System	29 Oct 2020 23:46:39
User entered '3'	System	21 Sep 2020 11:43:02
User entered '2'	System	10 Sep 2020 00:47:45
User entered '1'	System	07 Sep 2020 21:09:25

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:35:02

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:26:45
User entered '21/Sep/2020 07:43'	System	21 Sep 2020 11:43:02

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:35:02

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.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 23:46:26
User entered 'I'	(b) (4), (b) (6)	21 Sep 2020 11:43:02

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered		
'USA-US112-2020-MRNA-1273-P301000003'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered 'Jordan'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered 'Whatley'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered '5326 O'donovan dr'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered 'baton rouge'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 13:56:32
Un-reviewed for Safety.	System	29 Oct 2020 23:46:39
User entered empty.	System	29 Oct 2020 23:46:39
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 23:46:26
User entered 'LA'	(b) (4), (b) (6)	15 Oct 2020 19:52:34

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered '70808'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:33:50
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 00:47:30
User entered 'US' (non-conformant).	System	07 Sep 2020 21:09:25

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	20 Nov 2020 15:13:34
User entered '5'	System	05 Nov 2020 13:56:41
User entered '4'	System	29 Oct 2020 23:46:39
User entered '3'	System	21 Sep 2020 11:43:02
User entered '2'	System	10 Sep 2020 00:47:45
User entered '1'	System	07 Sep 2020 21:09:25

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:35:02

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:26:45
User entered '29/Oct/2020 19:46'	System	29 Oct 2020 23:46:39

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:35:02

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.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.		05 Nov 2020 13:56:32
User entered 'I'		29 Oct 2020 23:46:39

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered		
'USA-US112-2020-MRNA-1273-P301000003'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered 'Jordan'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered 'Whatley'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered '5326 O'donovan dr'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered 'baton rouge'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 13:56:32
Un-reviewed for Safety.	System	29 Oct 2020 23:46:39
User entered empty.	System	29 Oct 2020 23:46:39
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 23:46:26
User entered 'LA'	(b) (4), (b) (6)	15 Oct 2020 19:52:34

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered '70808'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:33:50
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 00:47:30
User entered 'US' (non-conformant).	System	07 Sep 2020 21:09:25

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	20 Nov 2020 15:13:34
User entered '5'	System	05 Nov 2020 13:56:41
User entered '4'	System	29 Oct 2020 23:46:39
User entered '3'	System	21 Sep 2020 11:43:02
User entered '2'	System	10 Sep 2020 00:47:45
User entered '1'	System	07 Sep 2020 21:09:25

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 22:35:02

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:26:45
User entered '05/Nov/2020 08:56'	System	05 Nov 2020 13:56:41

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 22:35:02

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.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 15:13:19
DataPoint Verified.		18 Nov 2020 21:26:45
User entered 'I'		05 Nov 2020 13:56:41

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered		
'USA-US112-2020-MRNA-1273-P301000003'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 21:09:19
User entered 'No (N)'	System	07 Sep 2020 21:06:53

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered 'Jordan'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered 'Whatley'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered '5326 O'donovan dr'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered 'baton rouge'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 13:56:32
Un-reviewed for Safety.	System	29 Oct 2020 23:46:39
User entered empty.	System	29 Oct 2020 23:46:39
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 23:46:26
User entered 'LA'	(b) (4), (b) (6)	15 Oct 2020 19:52:34

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Reviewed for Safety.	(b) (4), (b) (6)	21 Sep 2020 11:42:51
Amendment Manager: User entered '70808'	System	14 Sep 2020 21:47:03

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 21:26:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:33:50
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 00:47:30
User entered 'US' (non-conformant).	System	07 Sep 2020 21:09:25

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	20 Nov 2020 15:13:34
User entered '5'	System	05 Nov 2020 13:56:41
User entered '4'	System	29 Oct 2020 23:46:39
User entered '3'	System	21 Sep 2020 11:43:02
User entered '2'	System	10 Sep 2020 00:47:45
User entered '1'	System	07 Sep 2020 21:09:25

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 11 Aug 2021 22:35:02

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:41:14
User entered '20/Nov/2020 10:13'	System	20 Nov 2020 15:13:34

US3362083

Folder: SAE USA-US112-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 11 Aug 2021 22:35:02

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.	Jordan Whatley (b) (4)	24 Apr 2021 00:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 19:41:14
User entered 'I'	(b) (4), (b) (6)	20 Nov 2020 15:13:34