

US3312068 (Prod: Johnson County Clin-Trials)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:14:50

All time stamps listed in this document are displayed in GMT

US3312068

Form: Participant Creation

Data signed: (b) (4) 05 Apr 2021 17:34:42

Generated On: 11 Aug 2021 22:14:50

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[Participant ID](#)

US3312068

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

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US3312068

Folder: Screening

Form: Visit Date

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

Generated On: 11 Aug 2021 22:14:50

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

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Folder: Screening

Form: Demographics

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

Generated On: 11 Aug 2021 22:14:50

Date of Birth (MMM yyyy)	(b) (6) 1998
Age	21
Age Units	YEARS
Age (Derived)	21
Sex	Female <input checked="" type="radio"/> Male <input 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) 15 Feb 2021 21:45:45

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

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

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

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

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Were any significant conditions reported?

Yes ☐

No ☒

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Folder: Screening

Form: Vital Signs

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

Generated On: 11 Aug 2021 22:14:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 11:30
Height (xxx.x)	63 in
Weight (xxx.x)	143 lb
BMI (xxx.x)	25.38428 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



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Folder: Screening

Form: Physical Examination

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

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

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

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Date of assessment (dd MMM yyyy) 13 AUG 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

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

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Folder: Screening

Form: Pregnancy Test

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

Generated On: 11 Aug 2021 22:14:50

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 13 AUG 2020

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

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

US3312068

Folder: Screening

Form: Risk of Exposure

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

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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 ☐

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**Specify**

BABYSITS FOR UP TO FIVE FAMILIES

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

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

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 21:45:57

Generated On: 11 Aug 2021 22:14:50

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

Visit date (dd MMM yyyy)	13 AUG 2020
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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	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 21:45:56

Generated On: 11 Aug 2021 22:14:50

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

What was the participant's randomization number? 103944

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 21:45:57

Generated On: 11 Aug 2021 22:14:50

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) 15 Feb 2021 21:45:57

Generated On: 11 Aug 2021 22:14:50

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 11:30
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 21:45:57

Generated On: 11 Aug 2021 22:14:50

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	13:57 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 13:57
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

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

Generated On: 11 Aug 2021 22:14:50

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

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

Generated On: 11 Aug 2021 22:14:50

Was the pregnancy test performed? Yes ☐  
No ☒

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

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☐

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

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

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

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Folder: Visit 1 Day 1

Form: Exposure

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

Generated On: 11 Aug 2021 22:14:50

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 13:22 (24 HR)

Treatment Date and Time (derived) 13 AUG 2020 13:22

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) 15 Feb 2021 21:45:45

Generated On: 11 Aug 2021 22:14:50

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 AUG 2020

Collection time (00:00-23:59)

12:32 (24 HR)

Collection date and time (derived)

13 AUG 2020 12:32

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

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

Generated On: 11 Aug 2021 22:14:50

Collection date (dd MMM yyyy)			13 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:04	13 AUG 2020 12:04
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

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

Generated On: 11 Aug 2021 22:14:50

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 22:14:50

**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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 14:01

PC Open Date & Time

13 AUG 2020 13:42

PC Close Date & Time

13 AUG 2020 16:12

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.5 °F

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

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

PC Time Stamp	14 AUG 2020 10:18
PC Open Date & Time	13 AUG 2020 17:07
PC Close Date & Time	14 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:14:50

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**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

15 AUG 2020 08:22

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 20:01

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:14:50

**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

100.4 °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

16 AUG 2020 12:01

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

17 AUG 2020 13:05

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:14:50

**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

99.1 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

18 AUG 2020 12:13

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:14:50

**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

98.3 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

19 AUG 2020 13:05

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59



US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:14:50

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**TIMEPOINT**

DAY 8

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.4 °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

20 AUG 2020 12:00

---

PC Open Date & Time

20 AUG 2020 12:00

---

PC Close Date & Time

21 AUG 2020 11:59

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US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:14:50

**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

13 AUG 2020 14:01

PC Open Date & Time

13 AUG 2020 13:42

PC Close Date & Time

13 AUG 2020 16:12

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

**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

14 AUG 2020 10:18

PC Open Date & Time

13 AUG 2020 17:07

PC Close Date & Time

14 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:14:50

**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

15 AUG 2020 08:22

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 20:02

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 12:01

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 13:05

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 12:13

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59



US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 13:05

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:14:50

**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 ☐

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:14:50

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 14:01
PC Open Date & Time	13 AUG 2020 13:42
PC Close Date & Time	13 AUG 2020 16:12

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

**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 ☐

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 10:18
PC Open Date & Time	13 AUG 2020 17:07
PC Close Date & Time	14 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:14:50

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:14:50

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 08:22
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:14:50

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:14:50

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 20:02
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:14:50

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

49 of 2399

EAB) (1725)

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:14:50

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 12:02
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:14:50

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 13:06
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:14:50

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:14:50

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 12:14
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:14:50

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 ☒



US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:14:50

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 13:06
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

**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 ☐

PC Time Stamp 20 AUG 2020 12:01

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

**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 ☐

PC Time Stamp 21 AUG 2020 13:18

PC Open Date & Time 21 AUG 2020 12:00

PC Close Date & Time 22 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 11 Aug 2021 22:14:50

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**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your

**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 ☐

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PC Time Stamp

22 AUG 2020 12:29

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PC Open Date & Time

22 AUG 2020 12:00

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PC Close Date & Time

23 AUG 2020 11:59

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US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 11

Select one response below to indicate the intensity of your

**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 ☐

PC Time Stamp

23 AUG 2020 15:31

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(12)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 12

Select one response below to indicate the intensity of your

**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 ☐

PC Time Stamp

24 AUG 2020 16:57

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(13)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 13

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 12:00

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 20 AUG 2020 12:01

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59



US3312068

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

None ☒

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 21 AUG 2020 13:18

PC Open Date & Time 21 AUG 2020 12:00

PC Close Date & Time 22 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 8

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

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 20 AUG 2020 12:01

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 11 Aug 2021 22:14:50

---

**TIMEPOINT**

DAY 9

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

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

---

PC Time stamp 21 AUG 2020 13:18

PC Open Date & Time 21 AUG 2020 12:00

PC Close Date & Time 22 AUG 2020 11:59

---

US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 10

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

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 22 AUG 2020 12:30

PC Open Date & Time 22 AUG 2020 12:00

PC Close Date & Time 23 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(11)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 11

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

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 23 AUG 2020 15:31

PC Open Date & Time 23 AUG 2020 12:00

PC Close Date & Time 24 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(12)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 12

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

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 24 AUG 2020 16:57

PC Open Date & Time 24 AUG 2020 12:00

PC Close Date & Time 25 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(13)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 13

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

None ☒

**ACHES ALL OVER BODY**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 25 AUG 2020 12:00

PC Open Date & Time 25 AUG 2020 12:00

PC Close Date & Time 26 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 8

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

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

PC Time stamp 20 AUG 2020 12:01

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59



US3312068

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 9

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

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

PC Time stamp 21 AUG 2020 13:19

PC Open Date & Time 21 AUG 2020 12:00

PC Close Date & Time 22 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(10)

Generated On: 11 Aug 2021 22:14:50

---

**TIMEPOINT**

DAY 10

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

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

---

PC Time stamp 22 AUG 2020 12:30

PC Open Date & Time 22 AUG 2020 12:00

PC Close Date & Time 23 AUG 2020 11:59

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US3312068

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(11)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 11

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

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

PC Time stamp 23 AUG 2020 15:31

PC Open Date & Time 23 AUG 2020 12:00

PC Close Date & Time 24 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(12)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 12

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

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 24 AUG 2020 16:57

PC Open Date & Time 24 AUG 2020 12:00

PC Close Date & Time 25 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(8)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 8

Select one response below to indicate the level of your

**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 ☐

PC Time stamp 20 AUG 2020 12:01

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:14:50

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 AUG 2020 12:01
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:14:50

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 AUG 2020 13:19
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 11 Aug 2021 22:14:50

<b>TIMEPOINT</b>	DAY 10
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 AUG 2020 12:30
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59



US3312068

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 11 Aug 2021 22:14:50

<b>TIMEPOINT</b>	DAY 11
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 AUG 2020 15:31
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 11 Aug 2021 22:14:50

<b>TIMEPOINT</b>	DAY 12
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 AUG 2020 16:57
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3312068

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 11 Aug 2021 22:14:50

<b>TIMEPOINT</b>	DAY 13
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 AUG 2020 12:00
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3312068

Folder: Safety Call Day 8 (1)

Form: Safety Call

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

Generated On: 11 Aug 2021 22:14:50

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 20 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3312068

Folder: Safety Call Day 8 (1)

Form: Continuing

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

Generated On: 11 Aug 2021 22:14:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312068

Folder: Safety Call Day 15 (1)

Form: Safety Call

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

Generated On: 11 Aug 2021 22:14:50

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

US3312068

Folder: Safety Call Day 15 (1)

Form: Continuing

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

Generated On: 11 Aug 2021 22:14:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312068

Folder: Safety Call Day 22 (1)

Form: Safety Call

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

Generated On: 11 Aug 2021 22:14:50

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



US3312068

Folder: Safety Call Day 22 (1)

Form: Continuing

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

Generated On: 11 Aug 2021 22:14:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312068

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 21:45:57

Generated On: 11 Aug 2021 22:14:50

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

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 21:45:57

Generated On: 11 Aug 2021 22:14:50

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

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 21:45:57

Generated On: 11 Aug 2021 22:14:50

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

US3312068

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 21:45:57

Generated On: 11 Aug 2021 22:14:50

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.*

US3312068

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 21:45:57

Generated On: 11 Aug 2021 22:14:50

Was the pregnancy test performed? Yes ☐  
No ☒

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

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☐

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

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

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

US3312068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 21:45:57

Generated On: 11 Aug 2021 22:14:50

Was study treatment given? Yes ☐  
No ☒

If No, reason not given

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

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

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3312068

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 21:45:57

Generated On: 11 Aug 2021 22:14:50

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)



US3312068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 21:45:57

Generated On: 11 Aug 2021 22:14:50

Collection date (*dd MMM yyyy*)

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

US3312068

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:45:57

Generated On: 11 Aug 2021 22:14:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312068

Folder: Safety Call Day 36 (1)

Form: Safety Call

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

Generated On: 11 Aug 2021 22:14:50

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

US3312068

Folder: Safety Call Day 36 (1)

Form: Continuing

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

Generated On: 11 Aug 2021 22:14:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312068

Folder: Safety Call Day 43 (1)

Form: Safety Call

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

Generated On: 11 Aug 2021 22:14:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312068

Folder: Safety Call Day 43 (1)

Form: Continuing

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

Generated On: 11 Aug 2021 22:14:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312068

Folder: Safety Call Day 50 (1)

Form: Safety Call

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

Generated On: 11 Aug 2021 22:14:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312068

Folder: Safety Call Day 50 (1)

Form: Continuing

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

Generated On: 11 Aug 2021 22:14:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312068

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 21:45:57

Generated On: 11 Aug 2021 22:14:50

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

US3312068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 21:45:57

Generated On: 11 Aug 2021 22:14:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 OCT 2020
Time of assessment (00:00-23:59)	12:23 (24 HR)
Vital Signs Date and Time (derived)	08 OCT 2020 12:23
Temperature (xxx.x)	98.8 F
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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312068

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 21:45:57

Generated On: 11 Aug 2021 22:14:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 OCT 2020

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

US3312068

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 21:45:57

Generated On: 11 Aug 2021 22:14:50

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 OCT 2020

Collection time (00:00-23:59)

12:32 (24 HR)

Collection date and time (derived)

8 OCT 2020 12:32

US3312068

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:45:57

Generated On: 11 Aug 2021 22:14:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

<b>TIMEPOINT</b>	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	13 OCT 2020 00:01:30
Patient Cloud Open Date & Time	13 OCT 2020 00:01
Patient Cloud Close Date & Time	17 OCT 2020 23:59

US3312068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 OCT 2020 12:16:58

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3312068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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	27 OCT 2020 00:25:01
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59



US3312068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 00:01:22

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3312068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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	17 NOV 2020 00:13:06
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 103

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

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21 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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25 NOV 2020 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 DEC 2020 12:27:05
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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 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 DEC 2020 00:01:17
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 00:01:21
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 DEC 2020 16:27:26

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59



US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 DEC 2020 11:57:57

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**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

02 JAN 2021 00:28:34

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**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

10 JAN 2021 20:03:48

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 JAN 2021 13:17:12

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

<b>TIMEPOINT</b>	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	25 JAN 2021 15:25:25
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**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

03 FEB 2021 07:24:04

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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	08 FEB 2021 14:15:19
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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	15 FEB 2021 13:19:09
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59



US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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	20 FEB 2021 00:01:30
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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	02 MAR 2021 17:17:26
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**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

09 MAR 2021 10:12:21

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**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

13 MAR 2021 17:22:54

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 00:53:09

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**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

27 MAR 2021 00:17:30

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 APR 2021 12:03:49
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

<b>TIMEPOINT</b>	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	12 APR 2021 11:05:36
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59



US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**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

17 APR 2021 10:19:01

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**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

24 APR 2021 00:02:17

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**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

01 MAY 2021 11:57:21

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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="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"/>

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

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29 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUN 2021 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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"/>

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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 <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"/>



**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

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19 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUN 2021 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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"/>

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

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26 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 JUN 2021 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**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°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 ☐

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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"/>

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

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10 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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14 JUL 2021 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 341

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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"/>

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 355

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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"/>



**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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"/>

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**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 ☐



**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 SEP 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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"/>

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 418

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	02 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	06 OCT 2021 23:59
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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

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09 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 OCT 2021 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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"/>

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

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16 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 OCT 2021 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 439

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

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06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 NOV 2021 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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"/>

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 467

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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"/>

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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"/>



**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

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04 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 DEC 2021 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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"/>

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 DEC 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

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18 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 DEC 2021 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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"/>

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

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15 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JAN 2022 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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"/>

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

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12 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 FEB 2022 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**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 ☐

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

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19 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 FEB 2022 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

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26 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAR 2022 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

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05 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAR 2022 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**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°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 ☐

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

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12 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAR 2022 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**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°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 ☐



**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

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26 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAR 2022 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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"/>

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

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02 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 APR 2022 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**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°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 ☐

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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



**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

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23 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 APR 2022 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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°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"/>

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**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 ☐

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2022 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2022 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**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 ☐



**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

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28 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2022 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**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 ☐

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

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04 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUN 2022 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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"/>

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**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 ☐



**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

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18 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 JUN 2022 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**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 ☐

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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"/>

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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 JUL 2022 00:01

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13 JUL 2022 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 705

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐



**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

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16 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUL 2022 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 JUL 2022 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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

Date and time of submission

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30 JUL 2022 00:01

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03 AUG 2022 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

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06 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2022 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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"/>



**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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"/>

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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"/>

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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

Date and time of submission

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27 AUG 2022 00:01

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31 AUG 2022 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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°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"/>

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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07 SEP 2022 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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"/>



**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 SEP 2022 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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[Patient Cloud Open Date & Time](#)

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24 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 SEP 2022 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

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

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08 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

---

12 OCT 2022 23:59

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US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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"/>

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2022 23:59

US3312068

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:14:50

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		02 MAR 2021 17:17:36

US3312068

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312068

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312068

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312068

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312068

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312068

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312068

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312068

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312068

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

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

Visit date (dd MMM yyyy)	12 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
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US3312068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

Were vital signs assessed? Yes ☐  
No ☒

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

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

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3312068

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

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.*

US3312068

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 MAR 2021

Collection time (00:00-23:59)

13:36 (24 HR)

Collection date and time (derived)

12 MAR 2021 13:36



US3312068

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312068

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 19:25:20

Generated On: 11 Aug 2021 22:14:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312068

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 19:25:20

Generated On: 11 Aug 2021 22:14:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3312068**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:14:50**

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*

**US3312068**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:14:50**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) 05 Apr 2021 17:34:42

Generated On: 11 Aug 2021 22:14:50

Date of Contact	25 AUG 2020
Time of Contact	10:00
Date and Time of Contact (derived)	25 AUG 2020 10:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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"/>

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

	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	17 AUG 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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 ☐

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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"/>

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

	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	18 AUG 2020
------	-------------

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

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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 ☐

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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"/>

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

	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	19 AUG 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	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 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 (3)

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Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" 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 25 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

Symptom Day

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

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Form: Symptom Log (4)

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Generated On: 11 Aug 2021 22:14:50

	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	20 AUG 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (4)

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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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Form: Symptom Log (4)

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Generated On: 11 Aug 2021 22:14:50

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 (5)

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Symptom Day

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

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Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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

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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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	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 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 (5)

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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 (6)

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Symptom Day

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

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Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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

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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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	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 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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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 (7)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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

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Generated On: 11 Aug 2021 22:14:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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 25 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

Symptom Day

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

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Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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

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Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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

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Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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 25 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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 (9)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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

Date	25 AUG 2020
------	-------------

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

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

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

Temperature	98.0 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 type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input type="radio"/>
	Mild <input checked="" 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) 05 Apr 2021 17:34:43

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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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Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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 (10)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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 (10)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

	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 (10)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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

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Form: Symptom Log (11)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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 (11)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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

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Form: Symptom Log (11)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

	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 (11)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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 (12)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

	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	98 %	
O2 Saturation Units	%	
Temperature	96.6 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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)

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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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Form: Symptom Log (13)

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	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	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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	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 25 Aug 2020

Form: Symptom Log (13)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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 (14)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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 (14)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

	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	96 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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	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 25 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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 (15)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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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Form: Symptom Log (15)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

	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	99 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Generated On: 11 Aug 2021 22:14:50

	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 (15)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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 (16)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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 (16)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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

Date	01 SEP 2020
------	-------------

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

O2 Saturation	99 %
---------------	------

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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Form: Symptom Log (16)

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Generated On: 11 Aug 2021 22:14:50

	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 (16)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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 (17)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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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Form: Symptom Log (17)

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

Date	02 SEP 2020
------	-------------

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

O2 Saturation	100 %
---------------	-------

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

Temperature	96.6 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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	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 25 Aug 2020

Form: Symptom Log (17)

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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 (18)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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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Form: Symptom Log (18)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	03 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (18)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

	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 (18)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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 (19)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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 checked="" 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 (19)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	04 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
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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	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 (19)

Data signed: (b) (4) 05 Apr 2021 17:34:43

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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 (20)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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 checked="" 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 (20)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

	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	99 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (20)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

	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 (20)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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 (21)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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 checked="" 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 (21)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

	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	99 %	
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 (21)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

	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 25 Aug 2020

Form: Symptom Log (21)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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 25 Aug 2020

Form: Symptom Log (22)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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 checked="" 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 25 Aug 2020

Form: Symptom Log (22)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

	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	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (22)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

	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 25 Aug 2020

Form: Symptom Log (22)

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

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 25 Aug 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 05 Apr 2021 17:34:42

Generated On: 11 Aug 2021 22:14:50

Date of Visit	25 AUG 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	25 AUG 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Apr 2021 17:34:42

Generated On: 11 Aug 2021 22:14:50

Did the subject have Respiratory Rates  $\geq 30$  per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Respiratory Rate \_\_\_\_\_

Did the subject have Heart Rate  $\geq 125$  beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Oxygen Saturation \_\_\_\_\_

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date \_\_\_\_\_

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

Start Date \_\_\_\_\_

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Apr 2021 17:34:42

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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 25 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Apr 2021 17:34:42

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Hepatic Dysfunction? Yes ☐  
No ☐

Start Date

Neurologic Dysfunction? Yes ☐  
No ☐

Start Date

**Evidence of Pneumonia:**

Clinical Evidence Yes ☐  
No ☐

Date of Assessment

Radiographical Evidence Yes ☐  
No ☐

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐  
No ☒

Start Date

End Date

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 05 Apr 2021 17:34:43

Generated On: 11 Aug 2021 22:14:50

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	27 AUG 2020
Day 5	Yes	29 AUG 2020
Day 7	Yes	31 AUG 2020
Day 9	Yes	02 SEP 2020
Day 14	Yes	07 SEP 2020
Day 21	Yes	14 SEP 2020
Day 28	Yes	21 SEP 2020

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

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

Visit date (dd MMM yyyy)	25 AUG 2020
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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	SICKD1
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US3312068

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 AUG 2020
Time of assessment (00:00-23:59)	12:18 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 12:18
Height (xxx.x)	63 in
Weight (xxx.x)	141 lb
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312068

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 AUG 2020

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

US3312068

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

25 AUG 2020



US3312068

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 17:34:42

Generated On: 11 Aug 2021 22:14:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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

US3312068

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 14:41:50

Generated On: 11 Aug 2021 22:14:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	12:08 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 12:08
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312068

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 17:34:42

Generated On: 11 Aug 2021 22:14:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3312068

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 05 Apr 2021 17:34:42

Generated On: 11 Aug 2021 22:14:50

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

21 SEP 2020

US3312068

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

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

Visit date (dd MMM yyyy)	27 JAN 2021
--------------------------	-------------

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

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

Date of updated informed consent ( <i>dd MMM yyyy</i> )	27 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> )	27 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 type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	

US3312068

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 JAN 2021

Collection time (00:00-23:59)

14:16 (24 HR)

Collection date and time (derived)

27 JAN 2021 14:16

US3312068

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

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

Collection date (dd MMM yyyy)	27 JAN 2021
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Collection time (00:00 - 23:59)	14:15
---------------------------------	-------

Collection Date and Time (derived)	27 JAN 2021 14:15
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US3312068

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 15:44:32

Generated On: 11 Aug 2021 22:14:50

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3312068

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 15:44:32

Generated On: 11 Aug 2021 22:14:50

AEID	USA-US300-2020-MRNA-1273-P30 1000001
Adverse event	SYMPTOMATIC COVID 19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	17 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	28 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 15:44:32

Generated On: 11 Aug 2021 22:14:50

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	

US3312068

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 15:44:32

Generated On: 11 Aug 2021 22:14:50

---

IN RESPONSE TO QUERIES:  
ILLNESS VISIT DAY 1 WITH NP  
SWAB DONE 25AUG2020,  
RESULTS POSITIVE-REPORTED  
TO SITE ON 08SEP2020. HAD  
EXPOSURE OF COVID +  
INDIVIDUALS AT SCHOOL IN  
SAME RESIDENCE. SUBJECT  
ONLY TOOK IBUPROFEN FOR  
SYMPTOMS.

---

Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

---

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US3312068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Apr 2021 17:34:42

Generated On: 11 Aug 2021 22:14:50

---

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

Yes ☒

No ☐

---

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

---

US3312068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 17:34:42

Generated On: 11 Aug 2021 22:14:50

Name of Medication LO LOESTRIN

Prophylaxis Yes ☒  
No ☐

Indication BIRTH CONTROL

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 17:34:42

Generated On: 11 Aug 2021 22:14:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN AUG 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 17:34:42

Generated On: 11 Aug 2021 22:14:50

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)



US3312068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 17:34:42

Generated On: 11 Aug 2021 22:14:50

	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)		18 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)		19 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"/>

US3312068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Apr 2021 17:34:42

Generated On: 11 Aug 2021 22:14:50

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3312068

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

Date of dosing discontinuation (dd MMM yyyy) 28 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

US3312068

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:14:50

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 ☐

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

SAEID	USA-US300-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

SAEID	USA-US300-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/SEP/2020 08:47
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

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

SAEID	USA-US300-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	17/SEP/2020 08:42
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

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

SAEID	USA-US300-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	22/SEP/2020 11:21
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



US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

SAEID	USA-US300-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	27/OCT/2020 12:47
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

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 05 Apr 2021 17:34:44

Generated On: 11 Aug 2021 22:14:50

SAEID	USA-US300-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	11/NOV/2020 17:52
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

US3312068 (Prod: Johnson County Clin-Trials)

**US3312068**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:14:50**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'US3312068'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 17:24:39

US3312068

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:14:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 18:26:50

US3312068

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 17:24:40

US3312068

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	13 Aug 2020 18:26:50

**US3312068**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:14:50**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User entered 'SCRN'	System	13 Aug 2020 18:26:50



US3312068

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:14:50

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered (b) (6) 1998'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 17:24:41

US3312068

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:14:50

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '21'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 16:41:34

**US3312068**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:14:50**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User entered 'YEARS'	System	17 Aug 2020 16:41:34

**US3312068**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:14:50**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User entered '21'	System	13 Aug 2020 18:27:03

US3312068

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:14:50

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Female (F)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 16:41:34

US3312068

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:14:50

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 16:41:34

US3312068

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:14:50

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'I'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 16:41:34

US3312068

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:14:50

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 16:41:34



US3312068

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:14:50

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 16:41:34

US3312068

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:14:50

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 16:41:34

**US3312068**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:14:50**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 16:41:34

**US3312068**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:14:50**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 16:41:34

US3312068

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:14:50

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 16:41:34

**US3312068**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:14:50**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 16:41:34

**US3312068**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:14:50**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 16:41:34

US3312068

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:14:50

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '13 Aug 2020'	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 18:27:03



US3312068

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User entered 'Aug 2020'	System	13 Aug 2020 18:27:03

**US3312068**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:14:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User entered '2020'	System	13 Aug 2020 18:27:03

US3312068

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:14:50

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Amendment 2 (2)'	Christa Estrada (b) (4)	13 Aug 2020 18:27:03

US3312068

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 18:27:03

US3312068

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:14:50

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty.	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 18:27:03

US3312068

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:14:50

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty.	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 18:27:03

US3312068

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:14:50

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 18:27:03

US3312068

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:14:50

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 17:24:40



US3312068

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:14:50

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User entered 'I'	System	13 Aug 2020 18:27:28

US3312068

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 18:27:28

US3312068

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:14:50

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 16:41:48

US3312068

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 16:52:37

US3312068

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '13 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 16:52:37

US3312068

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '11:30'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 16:52:37

US3312068

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User entered '13 Aug 2020 11:30'	System	17 Aug 2020 16:52:37

US3312068

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '63' in	(b) (4) Karol Moore (b) (4)	17 Aug 2020 16:52:37
DataPoint set to visible.	(b) (4) System	13 Aug 2020 18:27:28



US3312068

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '143' lb	(b) (4) Karol Moore (b) (4)	17 Aug 2020 16:52:37
DataPoint set to visible.	(b) (4) System	13 Aug 2020 18:27:28

US3312068

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
Amendment Manager: User entered '25.38428'	System	16 Sep 2020 23:55:40
User entered '25.4'	System	17 Aug 2020 16:52:37
DataPoint set to visible.	System	13 Aug 2020 18:27:28

US3312068

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User entered 'kg/m2'	System	17 Aug 2020 16:52:37
DataPoint set to visible.	System	13 Aug 2020 18:27:28

US3312068

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	17 Aug 2020 16:52:37

US3312068

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 16:52:37

US3312068

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 16:52:37

US3312068

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	17 Aug 2020 16:52:37

**US3312068**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:14:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User entered 'bpm'	System	17 Aug 2020 16:52:37



US3312068

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	17 Aug 2020 16:52:37

US3312068

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User entered 'breaths/min'	System	17 Aug 2020 16:52:37

US3312068

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	17 Aug 2020 16:52:37

US3312068

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User entered 'mmHg'	System	17 Aug 2020 16:52:37

US3312068

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	17 Aug 2020 16:52:37

US3312068

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User entered 'mmHg'	System	17 Aug 2020 16:52:37

US3312068

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48

US3312068

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48



US3312068

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 16:53:28

US3312068

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	27 Aug 2020 12:57:50
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	27 Aug 2020 00:39:06
User entered '13 Aug 2020'	Karol Moore (b) (4) (b) (4)	17 Aug 2020 16:53:28

US3312068

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:14:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '13 Aug 2020'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:03:34

US3312068

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:03:34

US3312068

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:14:50

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty.	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:03:34

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:14:50

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty.	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:03:34

US3312068

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:03:34

US3312068

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:14:50

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:03:34



US3312068

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty.	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:03:34

US3312068

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:14:50

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '0'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:03:34

US3312068

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:14:50

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:03:46

US3312068

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:14:50

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	17 Aug 2020 20:11:38
User entered '13 Aug 2020' reason for change: Data Entry Error	Karol Moore (b) (4)	17 Aug 2020 20:11:38
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	17 Aug 2020 17:03:46
User entered empty.	Karol Moore (b) (4)	17 Aug 2020 17:03:46
	(b) (4)	

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Folder: Screening

Form: Pregnancy Test

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[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Urine (URINE)'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:03:46
	(b) (4)	

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Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:14:50

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Negative (NEGATIVE)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:03:46

US3312068

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:14:50

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:03:46

**US3312068**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:14:50**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty.	(b) (4)	17 Aug 2020 17:03:46
	Karol Moore (b) (4)	
	(b) (4)	



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Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:14:50

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:03:46

**US3312068**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:14:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User entered empty.	System	17 Aug 2020 17:03:46

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:04:44

US3312068

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:04:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:04:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:04:44

US3312068

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:04:44

US3312068

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:04:44



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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:04:44

US3312068

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:04:44

US3312068

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:04:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:04:44

US3312068

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:04:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:04:44

US3312068

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:50

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'babysits for up to five families'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:04:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:50

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:04:44



US3312068

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:04:44

US3312068

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'I'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:04:44

US3312068

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '0'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:04:44

US3312068

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:04:44

US3312068

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '0'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:04:44

US3312068

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:04:44

US3312068

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:50

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:56:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'resides in community with ongoing person to person transmission'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:04:44

US3312068

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:14:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 18:27:47



US3312068

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered '13 Aug 2020'	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 18:27:47

US3312068

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'Clinic (Clinic)'	(b) (4) Christa Estrada (b) (4) (b) (4)	13 Aug 2020 18:27:47

US3312068

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:14:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User entered 'VISIT1'	System	13 Aug 2020 18:27:47

US3312068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 17:50:31

US3312068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 04:14:41
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:14:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 17:50:31
User entered '103944' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 17:50:31

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 17:50:31

US3312068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'No (N)'	Christa Estrada (b) (4)	13 Aug 2020 18:29:05

US3312068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'No (N)'	Christa Estrada (b) (4)	13 Aug 2020 18:29:05



US3312068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 18:29:05

**US3312068**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:14:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 18:29:05

US3312068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:14:50

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 18:29:05

US3312068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	21 Oct 2020 19:57:57
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:19:56
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:04:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:14:50

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:14:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:14:50

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:14:50

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:19:50



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4)	17 Aug 2020 17:19:50
	(b) (4)	

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered '13 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered '11:30'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:19:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User entered '13 Aug 2020 11:30'	System	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered '98.7' F	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:19:50



US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered '64'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User entered 'bpm'	System	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User entered 'breaths/min'	System	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered '111'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User entered 'mmHg'	System	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered '66'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User entered 'mmHg'	System	17 Aug 2020 17:19:50



US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:14:50

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:14:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered '13 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	20 Aug 2020 12:44:24
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		17 Aug 2020 17:19:50
User entered '13:57'	Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User entered '13 Aug 2020 13:57'	System	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered '98.5' F	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:19:50



US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered '55'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User entered 'bpm'	System	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:19:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User entered 'breaths/min'	System	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered '119'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User entered 'mmHg'	System	17 Aug 2020 17:19:50



US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered '77'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User entered 'mmHg'	System	17 Aug 2020 17:19:50

US3312068

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	17 Aug 2020 17:20:15
User entered 'Yes (Y)'	Karol Moore (b) (4)	17 Aug 2020 17:20:01
	(b) (4)	

US3312068

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty; reason for change Data Entry Error	(b) (4)	17 Aug 2020 17:20:15
User entered '13 Aug 2020'	Karol Moore (b) (4)	17 Aug 2020 17:20:01
	(b) (4)	

US3312068

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:14:50

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User closed query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 09:35:49
Query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	15 Sep 2020 15:04:35
User entered 'No (N)' reason for change: Per Query Resolution	Karol Moore (b) (4) (b) (4)	15 Sep 2020 15:04:22
User opened query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 11:47:27
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:20:26

US3312068

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:14:50

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty; reason for change Per Query Resolution	(b) (4) Karol Moore (b) (4)	15 Sep 2020 15:04:22
User entered '13 Aug 2020'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:20:26
	(b) (4)	

US3312068

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:14:50

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty; reason for change Per Query Resolution	(b) (4) Karol Moore (b) (4)	15 Sep 2020 15:04:22
User entered 'Urine (URINE)'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:20:26
	(b) (4)	

US3312068

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:14:50

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty; reason for change Per Query Resolution	(b) (4)	15 Sep 2020 15:04:22
User entered 'Negative (NEGATIVE)'	Karol Moore (b) (4)	17 Aug 2020 17:20:26
	(b) (4)	



US3312068

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:14:50

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty; reason for change Per Query Resolution	(b) (4) Karol Moore (b) (4)	15 Sep 2020 15:04:22
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 17:20:26
	(b) (4)	

**US3312068**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:14:50**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:20:26

US3312068

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:14:50

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:20:26

US3312068

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User entered empty.	System	17 Aug 2020 17:20:26

US3312068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:14:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 18:30:18

US3312068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:14:50

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty.	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 18:30:18

US3312068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty.	Christa Estrada (b) (4)	13 Aug 2020 18:30:18

US3312068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:14:50

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 18:30:18



US3312068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:14:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '13 Aug 2020'	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 18:30:18

US3312068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '13:22'	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 18:30:18

US3312068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:14:50

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User entered '13 Aug 2020 13:22'	System	13 Aug 2020 18:30:18

US3312068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:14:50

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Left Arm (LEFT ARM)'	Christa Estrada (b) (4)	13 Aug 2020 18:30:18

US3312068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:14:50

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User entered 'ONCE'	System	13 Aug 2020 18:30:18

US3312068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:14:50

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 18:30:18

US3312068

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:20:53

US3312068

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '13 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:20:53



US3312068

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '12:32'	(b) (4)	17 Aug 2020 17:20:53
	Karol Moore (b) (4)	
	(b) (4)	

US3312068

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User entered '13 Aug 2020 12:32'	System	17 Aug 2020 17:20:53

US3312068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:14:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '13 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:21:05

US3312068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:14:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:21:05

US3312068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:14:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:21:05

US3312068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:14:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '12:04'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:21:05

**US3312068**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:14:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User entered '13 Aug 2020 12:04'	System	17 Aug 2020 17:21:05

US3312068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:14:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:21:05



US3312068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:14:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:21:05

US3312068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:14:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:21:05

**US3312068**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:14:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User entered empty.	System	17 Aug 2020 17:21:05

US3312068

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:14:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:21:11

**US3312068**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:14:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User entered 'I'	System	17 Aug 2020 17:21:11

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:14:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-13T14:00:57', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'd12709a0-e7d3-4734-b926-e740a2efa6f8' User entered 'Yes (Y)'	System	13 Aug 2020 19:01:20
	System	13 Aug 2020 19:01:20

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:14:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-13T14:01:09', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'd12709a0-e7d3-4734-b926-e740a2efa6f8' User entered '98.5'	System	13 Aug 2020 19:01:20
	System	13 Aug 2020 19:01:20



US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-13T14:01:13', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'd12709a0-e7d3-4734-b926-e740a2efa6f8'	System	13 Aug 2020 19:01:20
User entered 'No (N)'	System	13 Aug 2020 19:01:20

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-13T14:01:18', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'd12709a0-e7d3-4734-b926-e740a2efa6f8' User entered '13 Aug 2020 14:01'	System	13 Aug 2020 19:01:20
	System	13 Aug 2020 19:01:20

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '13 Aug 2020 13:42'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '13 Aug 2020 16:12'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-14T10:18:19', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '78d276c5-6925-47b0-b448-b76da219bb0d' User entered 'Yes (Y)'	System	14 Aug 2020 15:18:31
	System	14 Aug 2020 15:18:31

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-14T10:18:23', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '78d276c5-6925-47b0-b448-b76da219bb0d' User entered '98.5'	System	14 Aug 2020 15:18:31
	System	14 Aug 2020 15:18:31

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-14T10:18:26', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '78d276c5-6925-47b0-b448-b76da219bb0d'	System	14 Aug 2020 15:18:31
User entered 'No (N)'	System	14 Aug 2020 15:18:31



US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-14T10:18:28', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '78d276c5-6925-47b0-b448-b76da219bb0d' User entered '14 Aug 2020 10:18'	System	14 Aug 2020 15:18:31
	System	14 Aug 2020 15:18:31

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '13 Aug 2020 17:07'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 2'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:14:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T08:21:54', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'a91a8a79-3465-4579-bc4e-d7cfe5903113' User entered 'Yes (Y)'	System	15 Aug 2020 13:22:09
	System	15 Aug 2020 13:22:09

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:14:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T08:21:59', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'a91a8a79-3465-4579-bc4e-d7cfe5903113' User entered '97.2'	System	15 Aug 2020 13:22:09
	System	15 Aug 2020 13:22:09

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T08:22:06', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'a91a8a79-3465-4579-bc4e-d7cfe5903113'	System	15 Aug 2020 13:22:09
User entered 'No (N)'	System	15 Aug 2020 13:22:09

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:14:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T08:22:08', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'a91a8a79-3465-4579-bc4e-d7cfe5903113' User entered '15 Aug 2020 08:22'	System	15 Aug 2020 13:22:09
	System	15 Aug 2020 13:22:09



US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 3'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:14:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T20:01:51', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '4ae1da75-9384-41f8-88de-197bfe3a8976' User entered 'Yes (Y)'	System	16 Aug 2020 01:02:04
	System	16 Aug 2020 01:02:04

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:14:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T20:01:55', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '4ae1da75-9384-41f8-88de-197bfe3a8976' User entered '98.6'	System	16 Aug 2020 01:02:04
	System	16 Aug 2020 01:02:04

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T20:01:58', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '4ae1da75-9384-41f8-88de-197bfe3a8976'	System	16 Aug 2020 01:02:04
User entered 'No (N)'	System	16 Aug 2020 01:02:04

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:14:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T20:01:59', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '4ae1da75-9384-41f8-88de-197bfe3a8976'	System	16 Aug 2020 01:02:04
User entered '15 Aug 2020 20:01'	System	16 Aug 2020 01:02:04

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 18:30:18



US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 4'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:14:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-16T12:01:22', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '367decce-bfba-4cb2-8f37-bc060f468916' User entered 'Yes (Y)'	System	16 Aug 2020 17:01:34
	System	16 Aug 2020 17:01:34

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:14:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-16T12:01:27', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '367decce-bfba-4cb2-8f37-bc060f468916' User entered '100.4'	System	16 Aug 2020 17:01:34
	System	16 Aug 2020 17:01:34

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-16T12:01:29', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '367decce-bfba-4cb2-8f37-bc060f468916'	System	16 Aug 2020 17:01:34
User entered 'No (N)'	System	16 Aug 2020 17:01:34

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:14:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-16T12:01:31', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '367decce-bfba-4cb2-8f37-bc060f468916' User entered '16 Aug 2020 12:01'	System	16 Aug 2020 17:01:34
	System	16 Aug 2020 17:01:34

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 18:30:18



US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 5'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:14:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-17T13:04:42', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'faddf198-ad8f-491b-9256-6460d7b7e8d6'	System	17 Aug 2020 18:05:10
User entered 'Yes (Y)'	System	17 Aug 2020 18:05:10

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:14:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-17T13:04:47', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'faddf198-ad8f-491b-9256-6460d7b7e8d6'	System	17 Aug 2020 18:05:10
User entered '98.4'	System	17 Aug 2020 18:05:10

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-17T13:04:51', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'faddf198-ad8f-491b-9256-6460d7b7e8d6'	System	17 Aug 2020 18:05:10
User entered 'No (N)'	System	17 Aug 2020 18:05:10

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:14:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-17T13:05:06', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'faddf198-ad8f-491b-9256-6460d7b7e8d6'	System	17 Aug 2020 18:05:10
User entered '17 Aug 2020 13:05'	System	17 Aug 2020 18:05:10

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 6'	System	13 Aug 2020 18:30:18



US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:14:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-18T12:12:02', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '198f4cc7-84a0-40e6-93e4-3f2e5ea5e827'	System	18 Aug 2020 17:13:12
User entered 'Yes (Y)'	System	18 Aug 2020 17:13:12

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:14:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-18T12:12:07', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '198f4cc7-84a0-40e6-93e4-3f2e5ea5e827' User entered '99.1'	System	18 Aug 2020 17:13:12
	System	18 Aug 2020 17:13:12

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-18T12:12:11', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '198f4cc7-84a0-40e6-93e4-3f2e5ea5e827'	System	18 Aug 2020 17:13:12
User entered 'Yes (Y)'	System	18 Aug 2020 17:13:12

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CONTACT CONFIRMED. MEDICATION DETAILS ADDED TO CONCOMITANT MEDICATION PAGES' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 07:59:57
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-18T12:13:06', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '198f4cc7-84a0-40e6-93e4-3f2e5ea5e827'	Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:47:30
User entered '1'	System	18 Aug 2020 17:13:12
	System	18 Aug 2020 17:13:12
	System	18 Aug 2020 17:13:12

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:14:50

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-18T12:13:06', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '198f4cc7-84a0-40e6-93e4-3f2e5ea5e827' User entered '0'	System	18 Aug 2020 17:13:12
	System	18 Aug 2020 17:13:12

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:14:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-18T12:13:08', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '198f4cc7-84a0-40e6-93e4-3f2e5ea5e827'	System	18 Aug 2020 17:13:12
User entered '18 Aug 2020 12:13'	System	18 Aug 2020 17:13:12

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 18:30:18



US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 7'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:14:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-19T13:04:58', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '24ff03bd-3cee-4033-93a6-101d4b570c55'	System	19 Aug 2020 18:05:18
User entered 'Yes (Y)'	System	19 Aug 2020 18:05:18

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:14:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-19T13:05:06', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '24ff03bd-3cee-4033-93a6-101d4b570c55'	System	19 Aug 2020 18:05:18
User entered '98.3'	System	19 Aug 2020 18:05:18

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-19T13:05:09', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '24ff03bd-3cee-4033-93a6-101d4b570c55'	System	19 Aug 2020 18:05:18
User entered 'Yes (Y)'	System	19 Aug 2020 18:05:18

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CONTACT CONFIRMED. MEDICATION DETAILS ADDED TO CONCOMITANT MEDICATION PAGES' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 08:00:04
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-19T13:05:12', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '24ff03bd-3cee-4033-93a6-101d4b570c55' User entered '1'	Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:47:35
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	19 Aug 2020 18:05:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-19T13:05:12', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '24ff03bd-3cee-4033-93a6-101d4b570c55' User entered '1'	System	19 Aug 2020 18:05:18
User entered '1'	System	19 Aug 2020 18:05:18

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:14:50

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-19T13:05:12', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '24ff03bd-3cee-4033-93a6-101d4b570c55'	System	19 Aug 2020 18:05:18
User entered '0'	System	19 Aug 2020 18:05:18

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:14:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-19T13:05:13', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '24ff03bd-3cee-4033-93a6-101d4b570c55'	System	19 Aug 2020 18:05:18
User entered '19 Aug 2020 13:05'	System	19 Aug 2020 18:05:18

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 18:30:18



US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	18 Aug 2020 17:13:12
User entered 'Day 8'	System	18 Aug 2020 17:13:12

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:14:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-20T12:00:44', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'a11f1608-84b8-4461-baad-e76aff124a15'	System	20 Aug 2020 17:01:11
User entered 'Yes (Y)'	System	20 Aug 2020 17:01:11

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:14:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-20T12:00:48', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'a11f1608-84b8-4461-baad-e76aff124a15'	System	20 Aug 2020 17:01:11
User entered '98.4'	System	20 Aug 2020 17:01:11

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-20T12:00:50', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'a11f1608-84b8-4461-baad-e76aff124a15'	System	20 Aug 2020 17:01:11
User entered 'No (N)'	System	20 Aug 2020 17:01:11

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:14:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-20T12:00:51', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'a11f1608-84b8-4461-baad-e76aff124a15'	System	20 Aug 2020 17:01:11
User entered '20 Aug 2020 12:00'	System	20 Aug 2020 17:01:11

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 17:13:12

US3312068

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 17:13:12



US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:14:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-13T14:01:23', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '0c433483-c5e2-4cab-9836-8a686ff209b5'	System	13 Aug 2020 19:01:35
User entered 'None (1)'	System	13 Aug 2020 19:01:35

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:14:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-13T14:01:25', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '0c433483-c5e2-4cab-9836-8a686ff209b5'	System	13 Aug 2020 19:01:35
User entered 'No (N)'	System	13 Aug 2020 19:01:35

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-13T14:01:27', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '0c433483-c5e2-4cab-9836-8a686ff209b5' User entered 'No (N)'	System	13 Aug 2020 19:01:35
	System	13 Aug 2020 19:01:35

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:14:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-13T14:01:30', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '0c433483-c5e2-4cab-9836-8a686ff209b5'	System	13 Aug 2020 19:01:35
User entered 'None (1)'	System	13 Aug 2020 19:01:35

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:14:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-13T14:01:32', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '0c433483-c5e2-4cab-9836-8a686ff209b5' User entered '13 Aug 2020 14:01'	System	13 Aug 2020 19:01:35
	System	13 Aug 2020 19:01:35

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '13 Aug 2020 13:42'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '13 Aug 2020 16:12'	System	13 Aug 2020 18:30:18



US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-14T10:18:31', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '1c6eafee-c727-4828-b61f-b4bee6e5dee7'	System	14 Aug 2020 15:18:48
User entered 'None (1)'	System	14 Aug 2020 15:18:48

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-14T10:18:34', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '1c6eafee-c727-4828-b61f-b4bee6e5dee7'	System	14 Aug 2020 15:18:48
User entered 'No (N)'	System	14 Aug 2020 15:18:48

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-14T10:18:40', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '1c6eafee-c727-4828-b61f-b4bee6e5dee7' User entered 'No (N)'	System	14 Aug 2020 15:18:48
	System	14 Aug 2020 15:18:48

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-14T10:18:43', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '1c6eafee-c727-4828-b61f-b4bee6e5dee7'	System	14 Aug 2020 15:18:48
User entered 'None (1)'	System	14 Aug 2020 15:18:48

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-14T10:18:44', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '1c6eafee-c727-4828-b61f-b4bee6e5dee7'	System	14 Aug 2020 15:18:48
User entered '14 Aug 2020 10:18'	System	14 Aug 2020 15:18:48

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '13 Aug 2020 17:07'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 18:30:18



US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 2'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:14:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T08:22:10', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '0429e0c9-4876-455d-9832-e05781d4afb2'	System	15 Aug 2020 13:22:19
User entered 'None (1)'	System	15 Aug 2020 13:22:19

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:14:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T08:22:13', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '0429e0c9-4876-455d-9832-e05781d4afb2'	System	15 Aug 2020 13:22:19
User entered 'No (N)'	System	15 Aug 2020 13:22:19

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T08:22:14', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '0429e0c9-4876-455d-9832-e05781d4afb2'	System	15 Aug 2020 13:22:19
User entered 'No (N)'	System	15 Aug 2020 13:22:19

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:14:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T08:22:16', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '0429e0c9-4876-455d-9832-e05781d4afb2'	System	15 Aug 2020 13:22:19
User entered 'None (1)'	System	15 Aug 2020 13:22:19

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:14:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T08:22:18', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '0429e0c9-4876-455d-9832-e05781d4afb2'	System	15 Aug 2020 13:22:19
User entered '15 Aug 2020 08:22'	System	15 Aug 2020 13:22:19

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 18:30:18



US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 3'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:14:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T20:02:02', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '7737372c-c393-4c16-b0e0-77652da0f511'	System	16 Aug 2020 01:02:12
User entered 'None (1)'	System	16 Aug 2020 01:02:12

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:14:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T20:02:05', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '7737372c-c393-4c16-b0e0-77652da0f511'	System	16 Aug 2020 01:02:12
User entered 'No (N)'	System	16 Aug 2020 01:02:12

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T20:02:07', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '7737372c-c393-4c16-b0e0-77652da0f511' User entered 'No (N)'	System	16 Aug 2020 01:02:12
	System	16 Aug 2020 01:02:12

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:14:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T20:02:09', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '7737372c-c393-4c16-b0e0-77652da0f511'	System	16 Aug 2020 01:02:12
User entered 'None (1)'	System	16 Aug 2020 01:02:12

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:14:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T20:02:10', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '7737372c-c393-4c16-b0e0-77652da0f511'	System	16 Aug 2020 01:02:12
User entered '15 Aug 2020 20:02'	System	16 Aug 2020 01:02:12

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 18:30:18



US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 4'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:14:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-16T12:01:34', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'c070866d-3b33-4f10-9e73-297e6132eaf5'	System	16 Aug 2020 17:01:54
User entered 'None (1)'	System	16 Aug 2020 17:01:54

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:14:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-16T12:01:37', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'c070866d-3b33-4f10-9e73-297e6132eaf5'	System	16 Aug 2020 17:01:54
User entered 'No (N)'	System	16 Aug 2020 17:01:54

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-16T12:01:39', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'c070866d-3b33-4f10-9e73-297e6132eaf5'	System	16 Aug 2020 17:01:54
User entered 'No (N)'	System	16 Aug 2020 17:01:54

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:14:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-16T12:01:47', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'c070866d-3b33-4f10-9e73-297e6132eaf5'	System	16 Aug 2020 17:01:54
User entered 'None (1)'	System	16 Aug 2020 17:01:54

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:14:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-16T12:01:49', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'c070866d-3b33-4f10-9e73-297e6132eaf5' User entered '16 Aug 2020 12:01'	System	16 Aug 2020 17:01:54
	System	16 Aug 2020 17:01:54

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 18:30:18



US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 5'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:14:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-17T13:05:10', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b7810a49-4c53-4809-8393-ce4c22976570'	System	17 Aug 2020 18:05:32
User entered 'None (1)'	System	17 Aug 2020 18:05:32

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:14:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-17T13:05:14', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b7810a49-4c53-4809-8393-ce4c22976570'	System	17 Aug 2020 18:05:32
User entered 'No (N)'	System	17 Aug 2020 18:05:32

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-17T13:05:16', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b7810a49-4c53-4809-8393-ce4c22976570' User entered 'No (N)'	System	17 Aug 2020 18:05:32
	System	17 Aug 2020 18:05:32

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:14:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-17T13:05:24', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b7810a49-4c53-4809-8393-ce4c22976570'	System	17 Aug 2020 18:05:32
User entered 'None (1)'	System	17 Aug 2020 18:05:32

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:14:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-17T13:05:26', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b7810a49-4c53-4809-8393-ce4c22976570'	System	17 Aug 2020 18:05:32
User entered '17 Aug 2020 13:05'	System	17 Aug 2020 18:05:32

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 18:30:18



US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 6'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:14:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-18T12:13:12', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '3448f9e6-88c9-48da-84fd-d7b14d3a7e69'	System	18 Aug 2020 17:13:22
User entered 'None (1)'	System	18 Aug 2020 17:13:22

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:14:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-18T12:13:15', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '3448f9e6-88c9-48da-84fd-d7b14d3a7e69' User entered 'No (N)'	System	18 Aug 2020 17:13:22
	System	18 Aug 2020 17:13:22

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-18T12:13:17', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '3448f9e6-88c9-48da-84fd-d7b14d3a7e69' User entered 'No (N)'	System	18 Aug 2020 17:13:22
	System	18 Aug 2020 17:13:22

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:14:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-18T12:13:19', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '3448f9e6-88c9-48da-84fd-d7b14d3a7e69' User entered 'None (1)'	System	18 Aug 2020 17:13:22
	System	18 Aug 2020 17:13:22

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:14:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-18T12:13:20', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '3448f9e6-88c9-48da-84fd-d7b14d3a7e69'	System	18 Aug 2020 17:13:22
User entered '18 Aug 2020 12:13'	System	18 Aug 2020 17:13:22

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 18:30:18



US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 7'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:14:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-19T13:05:16', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b8b50d48-861f-43bb-a3d0-a2495507aa50'	System	19 Aug 2020 18:05:25
User entered 'None (1)'	System	19 Aug 2020 18:05:25

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:14:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-19T13:05:18', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b8b50d48-861f-43bb-a3d0-a2495507aa50'	System	19 Aug 2020 18:05:25
User entered 'No (N)'	System	19 Aug 2020 18:05:25

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-19T13:05:21', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b8b50d48-861f-43bb-a3d0-a2495507aa50'	System	19 Aug 2020 18:05:25
User entered 'No (N)'	System	19 Aug 2020 18:05:25

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:14:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-19T13:05:22', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b8b50d48-861f-43bb-a3d0-a2495507aa50'	System	19 Aug 2020 18:05:25
User entered 'None (1)'	System	19 Aug 2020 18:05:25

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:14:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-19T13:05:24', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b8b50d48-861f-43bb-a3d0-a2495507aa50'	System	19 Aug 2020 18:05:25
User entered '19 Aug 2020 13:05'	System	19 Aug 2020 18:05:25

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 18:30:18



US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:14:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-13T14:01:36', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '15246f4c-5c1b-4df1-8ace-fc51c7e37261' User entered 'None (0)'	System	13 Aug 2020 19:01:53
	System	13 Aug 2020 19:01:53

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:14:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-13T14:01:38', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '15246f4c-5c1b-4df1-8ace-fc51c7e37261' User entered 'None (0)'	System	13 Aug 2020 19:01:53
	System	13 Aug 2020 19:01:53

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:14:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-13T14:01:40', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '15246f4c-5c1b-4df1-8ace-fc51c7e37261' User entered 'None (0)'	System	13 Aug 2020 19:01:53
	System	13 Aug 2020 19:01:53

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:14:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-13T14:01:42', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '15246f4c-5c1b-4df1-8ace-fc51c7e37261' User entered 'None (0)'	System	13 Aug 2020 19:01:53
	System	13 Aug 2020 19:01:53

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:14:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-13T14:01:43', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '15246f4c-5c1b-4df1-8ace-fc51c7e37261' User entered 'None (0)'	System	13 Aug 2020 19:01:53
	System	13 Aug 2020 19:01:53

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:14:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-13T14:01:44', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '15246f4c-5c1b-4df1-8ace-fc51c7e37261' User entered 'None (0)'	System	13 Aug 2020 19:01:53
	System	13 Aug 2020 19:01:53

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:14:50

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)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-13T14:01:48', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '15246f4c-5c1b-4df1-8ace-fc51c7e37261' User entered 'No (N)'	System	13 Aug 2020 19:01:53
	System	13 Aug 2020 19:01:53



**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-13T14:01:50', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '15246f4c-5c1b-4df1-8ace-fc51c7e37261' User entered '13 Aug 2020 14:01'	System	13 Aug 2020 19:01:53
	System	13 Aug 2020 19:01:53

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
User entered '13 Aug 2020 13:42'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
User entered '13 Aug 2020 16:12'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-14T10:18:48', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'a0d9bcc0-38b8-43bf-8084-5bc42d526d42' User entered 'None (0)'	System	14 Aug 2020 15:19:03
	System	14 Aug 2020 15:19:03

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-14T10:18:49', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'a0d9bcc0-38b8-43bf-8084-5bc42d526d42' User entered 'None (0)'	System	14 Aug 2020 15:19:03
	System	14 Aug 2020 15:19:03

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-14T10:18:50', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'a0d9bcc0-38b8-43bf-8084-5bc42d526d42' User entered 'None (0)'	System	14 Aug 2020 15:19:03
	System	14 Aug 2020 15:19:03

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-14T10:18:52', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'a0d9bcc0-38b8-43bf-8084-5bc42d526d42' User entered 'None (0)'	System	14 Aug 2020 15:19:03
	System	14 Aug 2020 15:19:03



US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-14T10:18:53', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'a0d9bcc0-38b8-43bf-8084-5bc42d526d42' User entered 'None (0)'	System	14 Aug 2020 15:19:03
	System	14 Aug 2020 15:19:03

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-14T10:18:54', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'a0d9bcc0-38b8-43bf-8084-5bc42d526d42' User entered 'None (0)'	System	14 Aug 2020 15:19:03
	System	14 Aug 2020 15:19:03

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

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)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-14T10:18:58', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'a0d9bcc0-38b8-43bf-8084-5bc42d526d42'	System	14 Aug 2020 15:19:03
User entered 'No (N)'	System	14 Aug 2020 15:19:03

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-14T10:18:59', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'a0d9bcc0-38b8-43bf-8084-5bc42d526d42'	System	14 Aug 2020 15:19:03
User entered '14 Aug 2020 10:18'	System	14 Aug 2020 15:19:03

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
User entered '13 Aug 2020 17:07'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 2'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:14:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T08:22:21', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'e5efbc09-13e6-49e0-b5fd-e526049025ff' User entered 'None (0)'	System	15 Aug 2020 13:22:36
	System	15 Aug 2020 13:22:36



US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:14:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T08:22:23', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'e5efbc09-13e6-49e0-b5fd-e526049025ff' User entered 'None (0)'	System	15 Aug 2020 13:22:36
	System	15 Aug 2020 13:22:36

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:14:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T08:22:24', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'e5efbc09-13e6-49e0-b5fd-e526049025ff' User entered 'None (0)'	System	15 Aug 2020 13:22:36
	System	15 Aug 2020 13:22:36

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:14:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T08:22:28', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'e5efbc09-13e6-49e0-b5fd-e526049025ff' User entered 'None (0)'	System	15 Aug 2020 13:22:36
	System	15 Aug 2020 13:22:36

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:14:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T08:22:29', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'e5efbc09-13e6-49e0-b5fd-e526049025ff' User entered 'None (0)'	System	15 Aug 2020 13:22:36
	System	15 Aug 2020 13:22:36

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:14:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T08:22:31', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'e5efbc09-13e6-49e0-b5fd-e526049025ff' User entered 'None (0)'	System	15 Aug 2020 13:22:36
	System	15 Aug 2020 13:22:36

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:14:50

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)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T08:22:33', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'e5efbc09-13e6-49e0-b5fd-e526049025ff'	System	15 Aug 2020 13:22:36
User entered 'No (N)'	System	15 Aug 2020 13:22:36

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T08:22:34', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'e5efbc09-13e6-49e0-b5fd-e526049025ff' User entered '15 Aug 2020 08:22'	System	15 Aug 2020 13:22:36
	System	15 Aug 2020 13:22:36

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 18:30:18



US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 3'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:14:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T20:02:14', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '129825cc-e545-44d5-a901-04483d628790'	System	16 Aug 2020 01:02:31
User entered 'No interference with activity (1)'	System	16 Aug 2020 01:02:31

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:14:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T20:02:17', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '129825cc-e545-44d5-a901-04483d628790' User entered 'None (0)'	System	16 Aug 2020 01:02:31
	System	16 Aug 2020 01:02:31

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:14:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T20:02:19', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '129825cc-e545-44d5-a901-04483d628790' User entered 'None (0)'	System	16 Aug 2020 01:02:31
	System	16 Aug 2020 01:02:31

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:14:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T20:02:21', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '129825cc-e545-44d5-a901-04483d628790' User entered 'None (0)'	System	16 Aug 2020 01:02:31
	System	16 Aug 2020 01:02:31

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:14:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T20:02:23', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '129825cc-e545-44d5-a901-04483d628790' User entered 'None (0)'	System	16 Aug 2020 01:02:31
	System	16 Aug 2020 01:02:31

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:14:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T20:02:25', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '129825cc-e545-44d5-a901-04483d628790' User entered 'None (0)'	System	16 Aug 2020 01:02:31
	System	16 Aug 2020 01:02:31



US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:14:50

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)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T20:02:28', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '129825cc-e545-44d5-a901-04483d628790'	System	16 Aug 2020 01:02:31
User entered 'No (N)'	System	16 Aug 2020 01:02:31

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:14:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-15T20:02:29', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '129825cc-e545-44d5-a901-04483d628790'	System	16 Aug 2020 01:02:31
User entered '15 Aug 2020 20:02'	System	16 Aug 2020 01:02:31

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 4'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:14:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-16T12:01:56', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '2c0c36de-8eaa-4a75-9a17-c6201b774099' User entered 'None (0)'	System	16 Aug 2020 17:02:12
	System	16 Aug 2020 17:02:12

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:14:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-16T12:01:58', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '2c0c36de-8eaa-4a75-9a17-c6201b774099' User entered 'None (0)'	System	16 Aug 2020 17:02:12
	System	16 Aug 2020 17:02:12

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:14:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-16T12:02:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '2c0c36de-8eaa-4a75-9a17-c6201b774099' User entered 'None (0)'	System	16 Aug 2020 17:02:12
	System	16 Aug 2020 17:02:12



US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:14:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-16T12:02:02', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '2c0c36de-8eaa-4a75-9a17-c6201b774099' User entered 'None (0)'	System	16 Aug 2020 17:02:12
	System	16 Aug 2020 17:02:12

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:14:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-16T12:02:04', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '2c0c36de-8eaa-4a75-9a17-c6201b774099' User entered 'None (0)'	System	16 Aug 2020 17:02:12
	System	16 Aug 2020 17:02:12

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:14:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-16T12:02:05', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '2c0c36de-8eaa-4a75-9a17-c6201b774099' User entered 'None (0)'	System	16 Aug 2020 17:02:12
	System	16 Aug 2020 17:02:12

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:14:50

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)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-16T12:02:08', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '2c0c36de-8eaa-4a75-9a17-c6201b774099'	System	16 Aug 2020 17:02:12
User entered 'No (N)'	System	16 Aug 2020 17:02:12

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:14:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-16T12:02:10', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '2c0c36de-8eaa-4a75-9a17-c6201b774099' User entered '16 Aug 2020 12:02'	System	16 Aug 2020 17:02:12
	System	16 Aug 2020 17:02:12

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 5'	System	13 Aug 2020 18:30:18



US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:14:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-17T13:05:39', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'f9436a21-689a-4ee9-b381-799f7d45f78a'	System	17 Aug 2020 18:06:34
User entered 'No interference with activity (1)'	System	17 Aug 2020 18:06:34

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:14:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-17T13:05:42', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'f9436a21-689a-4ee9-b381-799f7d45f78a'	System	17 Aug 2020 18:06:34
User entered 'Some interference with activity (2)'	System	17 Aug 2020 18:06:34

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:14:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-17T13:05:50', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'f9436a21-689a-4ee9-b381-799f7d45f78a' User entered 'None (0)'	System	17 Aug 2020 18:06:34
	System	17 Aug 2020 18:06:34

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:14:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-17T13:06:01', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'f9436a21-689a-4ee9-b381-799f7d45f78a' User entered 'None (0)'	System	17 Aug 2020 18:06:34
	System	17 Aug 2020 18:06:34

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:14:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-17T13:06:05', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'f9436a21-689a-4ee9-b381-799f7d45f78a' User entered 'None (0)'	System	17 Aug 2020 18:06:34
	System	17 Aug 2020 18:06:34

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:14:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-17T13:06:07', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'f9436a21-689a-4ee9-b381-799f7d45f78a' User entered 'None (0)'	System	17 Aug 2020 18:06:34
	System	17 Aug 2020 18:06:34

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:14:50

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)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-17T13:06:29', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'f9436a21-689a-4ee9-b381-799f7d45f78a' User entered 'No (N)'	System	17 Aug 2020 18:06:34
	System	17 Aug 2020 18:06:34

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:14:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-17T13:06:31', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'f9436a21-689a-4ee9-b381-799f7d45f78a'	System	17 Aug 2020 18:06:34
User entered '17 Aug 2020 13:06'	System	17 Aug 2020 18:06:34



US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 6'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:14:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
User closed query 'Per DM CLR: Per Diary Dose 1 Day 6 and 7, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 08:53:36
Query 'Per DM CLR: Per Diary Dose 1 Day 6 and 7, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' answered with 'CONFIRMED WITH SUBJECT. CORRECT AS ENTERED. CORRESPONDING CON MED LISTED ON LINE 2 OF CON MED PAGE HEADACHE WAS A COVID-19 SYMPTOM. CON MED INDICATION CHANGED AFTER COVID-19 POSITIVE TEST RESULT.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 17:03:47
User opened query 'Per DM CLR: Per Diary Dose 1 Day 6 and 7, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 15:13:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-18T12:13:38', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b7117abb-f411-4256-89cc-93b50b11b898'	System	18 Aug 2020 17:14:10

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:14:50

**HEADACHE**

Audit	User	Time (GMT)
User entered 'Repeated use of over-the-counter pain reliever &gt; 24 hours or some interference with activity (2)'	System	18 Aug 2020 17:14:10

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:14:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-18T12:13:42', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b7117abb-f411-4256-89cc-93b50b11b898'	System	18 Aug 2020 17:14:10
User entered 'Some interference with activity (2)'	System	18 Aug 2020 17:14:10

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:14:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-18T12:13:46', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b7117abb-f411-4256-89cc-93b50b11b898'	System	18 Aug 2020 17:14:10
User entered 'Some interference with activity (2)'	System	18 Aug 2020 17:14:10

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:14:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-18T12:13:52', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b7117abb-f411-4256-89cc-93b50b11b898'	System	18 Aug 2020 17:14:10
User entered 'No interference with activity (1)'	System	18 Aug 2020 17:14:10



US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:14:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-18T12:13:55', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b7117abb-f411-4256-89cc-93b50b11b898' User entered 'None (0)'	System	18 Aug 2020 17:14:10
	System	18 Aug 2020 17:14:10

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:14:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-18T12:13:58', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b7117abb-f411-4256-89cc-93b50b11b898' User entered 'None (0)'	System	18 Aug 2020 17:14:10
	System	18 Aug 2020 17:14:10

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:14:50

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)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-18T12:14:08', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b7117abb-f411-4256-89cc-93b50b11b898'	System	18 Aug 2020 17:14:10
User entered 'No (N)'	System	18 Aug 2020 17:14:10

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:14:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-18T12:14:09', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b7117abb-f411-4256-89cc-93b50b11b898'	System	18 Aug 2020 17:14:10
User entered '18 Aug 2020 12:14'	System	18 Aug 2020 17:14:10

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 7'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:14:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-19T13:05:44', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'cf04df4b-696a-43ac-bad9-b4c7da8e137e'	System	19 Aug 2020 18:06:16
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	19 Aug 2020 18:06:16



US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:14:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-19T13:05:49', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'cf04df4b-696a-43ac-bad9-b4c7da8e137e'	System	19 Aug 2020 18:06:16
User entered 'Some interference with activity (2)'	System	19 Aug 2020 18:06:16

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:14:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-19T13:05:52', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'cf04df4b-696a-43ac-bad9-b4c7da8e137e'	System	19 Aug 2020 18:06:16
User entered 'Some interference with activity (2)'	System	19 Aug 2020 18:06:16

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:14:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-19T13:05:56', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'cf04df4b-696a-43ac-bad9-b4c7da8e137e' User entered 'Some interference with activity (2)'	System	19 Aug 2020 18:06:16
	System	19 Aug 2020 18:06:16

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:14:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-19T13:06:07', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'cf04df4b-696a-43ac-bad9-b4c7da8e137e'	System	19 Aug 2020 18:06:16
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	19 Aug 2020 18:06:16

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:14:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-19T13:06:10', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'cf04df4b-696a-43ac-bad9-b4c7da8e137e' User entered 'None (0)'	System	19 Aug 2020 18:06:16
	System	19 Aug 2020 18:06:16

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:14:50

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)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-19T13:06:12', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'cf04df4b-696a-43ac-bad9-b4c7da8e137e' User entered 'No (N)'	System	19 Aug 2020 18:06:16
	System	19 Aug 2020 18:06:16

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-19T13:06:14', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'cf04df4b-696a-43ac-bad9-b4c7da8e137e' User entered '19 Aug 2020 13:06'	System	19 Aug 2020 18:06:16
	System	19 Aug 2020 18:06:16

US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 18:30:18



US3312068

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Mar 2021 00:49:43
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 18:30:18

US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	18 Aug 2020 17:14:10
User entered 'Day 8'	System	18 Aug 2020 17:14:10

US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-20T12:01:04', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b27cfc07-d632-4949-bde7-89cdf81e0e19'	System	20 Aug 2020 17:01:29
User entered 'No interference with activity (1)'	System	20 Aug 2020 17:01:29

US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:14:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-20T12:01:06', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b27cfc07-d632-4949-bde7-89cdf81e0e19' User entered '20 Aug 2020 12:01'	System	20 Aug 2020 17:01:29
	System	20 Aug 2020 17:01:29

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 17:14:10

US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 17:14:10

US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	19 Aug 2020 18:06:16
User entered 'Day 9'	System	19 Aug 2020 18:06:16

US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-21T13:18:30', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'cec1e670-d0d3-4479-896e-bebb0588fbf7'	System	21 Aug 2020 18:18:36
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	21 Aug 2020 18:18:36



US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 11 Aug 2021 22:14:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-21T13:18:31', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'cec1e670-d0d3-4479-896e-bebb0588fbf7'	System	21 Aug 2020 18:18:36
User entered '21 Aug 2020 13:18'	System	21 Aug 2020 18:18:36

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(9)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 18:06:16

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(9)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 18:06:16

US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	20 Aug 2020 17:01:29
User entered 'Day 10'	System	20 Aug 2020 17:01:29

US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-22T12:29:57', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '6083d6f5-eea5-4019-8783-7bfc03125e60'	System	22 Aug 2020 17:30:02
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	22 Aug 2020 17:30:02

US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 11 Aug 2021 22:14:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-22T12:29:59', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '6083d6f5-eea5-4019-8783-7bfc03125e60' User entered '22 Aug 2020 12:29'	System	22 Aug 2020 17:30:02
	System	22 Aug 2020 17:30:02

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(10)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:01:29

US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:01:29



US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	21 Aug 2020 18:18:36
User entered 'Day 11'	System	21 Aug 2020 18:18:36

US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-23T15:31:19', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'a1c7237f-25d4-4e1b-8437-2b8281a8620e'	System	23 Aug 2020 20:31:25
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	23 Aug 2020 20:31:25

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(11)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-23T15:31:21', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'a1c7237f-25d4-4e1b-8437-2b8281a8620e' User entered '23 Aug 2020 15:31'	System	23 Aug 2020 20:31:25
	System	23 Aug 2020 20:31:25

US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 18:18:36

US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 18:18:36

US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(12)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	22 Aug 2020 17:30:02
User entered 'Day 12'	System	22 Aug 2020 17:30:02

US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(12)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-24T16:57:25', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'a0dc3dd3-1594-4b03-96ca-cc4b271a9dce'	System	24 Aug 2020 21:57:29
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	24 Aug 2020 21:57:29

US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(12)

Generated On: 11 Aug 2021 22:14:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-24T16:57:27', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'a0dc3dd3-1594-4b03-96ca-cc4b271a9dce' User entered '24 Aug 2020 16:57'	System	24 Aug 2020 21:57:29
	System	24 Aug 2020 21:57:29



US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(12)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 17:30:02

US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(12)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 17:30:02

US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(13)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	23 Aug 2020 20:31:25
User entered 'Day 13'	System	23 Aug 2020 20:31:25

US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(13)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-25T12:00:09', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '4eb44fcb-9e61-469d-a457-d5e938ea594a' User entered 'None (0)'	System	25 Aug 2020 17:00:17
	System	25 Aug 2020 17:00:17

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(13)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-25T12:00:11', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '4eb44fcb-9e61-469d-a457-d5e938ea594a' User entered '25 Aug 2020 12:00'	System	25 Aug 2020 17:00:17
	System	25 Aug 2020 17:00:17

US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(13)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 20:31:25

US3312068

Folder: Diary Dose 1 (1)

Form: Headache\_Day(13)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 20:31:25

US3312068

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	18 Aug 2020 17:14:10
User entered 'Day 8'	System	18 Aug 2020 17:14:10



US3312068

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-20T12:01:17', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'a8876357-fddc-4fd7-8e86-ae48a4247720'	System	20 Aug 2020 17:01:44
User entered 'No interference with activity (1)'	System	20 Aug 2020 17:01:44

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-20T12:01:19', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'a8876357-fddc-4fd7-8e86-ae48a4247720' User entered '20 Aug 2020 12:01'	System	20 Aug 2020 17:01:44
	System	20 Aug 2020 17:01:44

US3312068

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 17:14:10

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 17:14:10

US3312068

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	19 Aug 2020 18:06:16
User entered 'Day 9'	System	19 Aug 2020 18:06:16

US3312068

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-21T13:18:47', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'ca2b6697-2ae2-4587-b7d6-1303eaa46a7a' User entered 'None (0)'	System	21 Aug 2020 18:18:50
	System	21 Aug 2020 18:18:50

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-21T13:18:48', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'ca2b6697-2ae2-4587-b7d6-1303eaa46a7a'	System	21 Aug 2020 18:18:50
User entered '21 Aug 2020 13:18'	System	21 Aug 2020 18:18:50

US3312068

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 18:06:16



**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 18:06:16

US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	18 Aug 2020 17:14:10
User entered 'Day 8'	System	18 Aug 2020 17:14:10

US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 11 Aug 2021 22:14:50

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-20T12:01:24', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '8c36a573-e2d7-4be3-af93-93143ff16b09'	System	20 Aug 2020 17:01:47
User entered 'Some interference with activity (2)'	System	20 Aug 2020 17:01:47

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-20T12:01:26', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '8c36a573-e2d7-4be3-af93-93143ff16b09'	System	20 Aug 2020 17:01:47
User entered '20 Aug 2020 12:01'	System	20 Aug 2020 17:01:47

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 17:14:10

US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 17:14:10

US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	19 Aug 2020 18:06:16
User entered 'Day 9'	System	19 Aug 2020 18:06:16

US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 11 Aug 2021 22:14:50

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-21T13:18:53', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '7d9c1389-343a-4883-9604-e1cf9ca7780a'	System	21 Aug 2020 18:18:57
User entered 'Some interference with activity (2)'	System	21 Aug 2020 18:18:57



US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 11 Aug 2021 22:14:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-21T13:18:55', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '7d9c1389-343a-4883-9604-e1cf9ca7780a'	System	21 Aug 2020 18:18:57
User entered '21 Aug 2020 13:18'	System	21 Aug 2020 18:18:57

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(9)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 18:06:16

US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 18:06:16

US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	20 Aug 2020 17:01:47
User entered 'Day 10'	System	20 Aug 2020 17:01:47

US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 11 Aug 2021 22:14:50

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-22T12:30:04', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '4ad7f780-fb69-48a7-8bd1-a027c687f0d3'	System	22 Aug 2020 17:30:10
User entered 'Some interference with activity (2)'	System	22 Aug 2020 17:30:10

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(10)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-22T12:30:05', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '4ad7f780-fb69-48a7-8bd1-a027c687f0d3'	System	22 Aug 2020 17:30:10
User entered '22 Aug 2020 12:30'	System	22 Aug 2020 17:30:10

US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:01:47

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(10)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:01:47



US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(11)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	21 Aug 2020 18:18:57
User entered 'Day 11'	System	21 Aug 2020 18:18:57

US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(11)

Generated On: 11 Aug 2021 22:14:50

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-23T15:31:32', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '2f5ace3c-1c22-4c6d-abfb-fd561e06c4c6'	System	23 Aug 2020 20:32:05
User entered 'No interference with activity (1)'	System	23 Aug 2020 20:32:05

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(11)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-23T15:31:35', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '2f5ace3c-1c22-4c6d-abfb-fd561e06c4c6' User entered '23 Aug 2020 15:31'	System	23 Aug 2020 20:32:05
	System	23 Aug 2020 20:32:05

US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(11)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 18:18:57

US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(11)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 18:18:57

US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(12)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	22 Aug 2020 17:30:10
User entered 'Day 12'	System	22 Aug 2020 17:30:10

US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(12)

Generated On: 11 Aug 2021 22:14:50

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-24T16:57:40', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '987b0e95-206e-426c-89aa-c5a364bc5817'	System	24 Aug 2020 21:57:44
User entered 'No interference with activity (1)'	System	24 Aug 2020 21:57:44

US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(12)

Generated On: 11 Aug 2021 22:14:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-24T16:57:42', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '987b0e95-206e-426c-89aa-c5a364bc5817' User entered '24 Aug 2020 16:57'	System	24 Aug 2020 21:57:44
	System	24 Aug 2020 21:57:44



US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(12)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 17:30:10

US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(12)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 17:30:10

US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(13)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	23 Aug 2020 20:32:05
User entered 'Day 13'	System	23 Aug 2020 20:32:05

US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(13)

Generated On: 11 Aug 2021 22:14:50

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-25T12:00:15', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '696ab0ac-084c-4075-b11b-33a8f66a2cda' User entered 'None (0)'	System	25 Aug 2020 17:00:20
	System	25 Aug 2020 17:00:20

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(13)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-25T12:00:16', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '696ab0ac-084c-4075-b11b-33a8f66a2cda' User entered '25 Aug 2020 12:00'	System	25 Aug 2020 17:00:20
	System	25 Aug 2020 17:00:20

US3312068

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(13)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 20:32:05

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(13)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 20:32:05

US3312068

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	18 Aug 2020 17:14:10
User entered 'Day 8'	System	18 Aug 2020 17:14:10



US3312068

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-20T12:01:32', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b84ef0c4-437f-41c2-ad91-c7afbdf19133'	System	20 Aug 2020 17:01:51
User entered 'Some interference with activity (2)'	System	20 Aug 2020 17:01:51

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-20T12:01:34', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b84ef0c4-437f-41c2-ad91-c7afbdf19133'	System	20 Aug 2020 17:01:51
User entered '20 Aug 2020 12:01'	System	20 Aug 2020 17:01:51

US3312068

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 17:14:10

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 17:14:10

US3312068

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	19 Aug 2020 18:06:16
User entered 'Day 9'	System	19 Aug 2020 18:06:16

US3312068

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-21T13:19:01', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'a9c5d647-7e9f-4fd2-b1b9-227b5b33518a'	System	21 Aug 2020 18:19:05
User entered 'Some interference with activity (2)'	System	21 Aug 2020 18:19:05

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-21T13:19:02', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'a9c5d647-7e9f-4fd2-b1b9-227b5b33518a' User entered '21 Aug 2020 13:19'	System	21 Aug 2020 18:19:05
	System	21 Aug 2020 18:19:05

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 18:06:16



**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 18:06:16

US3312068

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(10)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	20 Aug 2020 17:01:51
User entered 'Day 10'	System	20 Aug 2020 17:01:51

US3312068

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(10)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-22T12:30:08', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '9d3d0b66-593b-40cf-87b1-d735a5343347'	System	22 Aug 2020 17:30:11
User entered 'Some interference with activity (2)'	System	22 Aug 2020 17:30:11

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(10)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-22T12:30:10', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '9d3d0b66-593b-40cf-87b1-d735a5343347'	System	22 Aug 2020 17:30:11
User entered '22 Aug 2020 12:30'	System	22 Aug 2020 17:30:11

US3312068

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(10)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:01:51

US3312068

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(10)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:01:51

US3312068

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(11)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	21 Aug 2020 18:19:05
User entered 'Day 11'	System	21 Aug 2020 18:19:05

US3312068

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(11)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-23T15:31:45', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '4b0f2942-31da-468e-84da-70a6507c7153'	System	23 Aug 2020 20:32:12
User entered 'Some interference with activity (2)'	System	23 Aug 2020 20:32:12



**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(11)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-23T15:31:46', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '4b0f2942-31da-468e-84da-70a6507c7153'	System	23 Aug 2020 20:32:12
User entered '23 Aug 2020 15:31'	System	23 Aug 2020 20:32:12

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(11)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 18:19:05

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(11)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 18:19:05

US3312068

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(12)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	22 Aug 2020 17:30:11
User entered 'Day 12'	System	22 Aug 2020 17:30:11

US3312068

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(12)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-24T16:57:49', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'c49086fb-a67a-4315-a3fc-c22a2a1d98ed' User entered 'None (0)'	System	24 Aug 2020 21:57:54
	System	24 Aug 2020 21:57:54

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(12)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-24T16:57:51', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'c49086fb-a67a-4315-a3fc-c22a2a1d98ed' User entered '24 Aug 2020 16:57'	System	24 Aug 2020 21:57:54
	System	24 Aug 2020 21:57:54

US3312068

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(12)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 17:30:11

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(12)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 17:30:11



US3312068

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(8)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	19 Aug 2020 18:06:16
User entered 'Day 8'	System	19 Aug 2020 18:06:16

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: Nausea\_Day(8)**

**Generated On: 11 Aug 2021 22:14:50**

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-20T12:01:38', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'dbb0002b-6156-4adc-93fc-260a86786a86' User entered 'None (0)'	System	20 Aug 2020 17:01:53
	System	20 Aug 2020 17:01:53

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: Nausea\_Day(8)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-20T12:01:40', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'dbb0002b-6156-4adc-93fc-260a86786a86' User entered '20 Aug 2020 12:01'	System	20 Aug 2020 17:01:53
	System	20 Aug 2020 17:01:53

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: Nausea\_Day(8)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 18:06:16

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: Nausea\_Day(8)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 18:06:16

US3312068

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	18 Aug 2020 17:13:12
User entered 'Day 8'	System	18 Aug 2020 17:13:12

US3312068

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-20T12:01:43', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'e01e506a-796d-4a80-b80c-d0d91fb83ab7' User entered 'No (N)'	System	20 Aug 2020 17:01:57
	System	20 Aug 2020 17:01:57

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-20T12:01:45', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'e01e506a-796d-4a80-b80c-d0d91fb83ab7' User entered '20 Aug 2020 12:01'	System	20 Aug 2020 17:01:57
	System	20 Aug 2020 17:01:57



US3312068

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 17:13:12

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 17:13:12

US3312068

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	19 Aug 2020 18:05:18
User entered 'Day 9'	System	19 Aug 2020 18:05:18

US3312068

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-21T13:19:06', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '3eb6a24a-8198-4986-bf5c-f638fbb75516'	System	21 Aug 2020 18:19:10
User entered 'No (N)'	System	21 Aug 2020 18:19:10

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-21T13:19:08', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '3eb6a24a-8198-4986-bf5c-f638fbb75516'	System	21 Aug 2020 18:19:10
User entered '21 Aug 2020 13:19'	System	21 Aug 2020 18:19:10

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 18:05:18

US3312068

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 18:05:18

US3312068

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	20 Aug 2020 17:01:29
User entered 'Day 10'	System	20 Aug 2020 17:01:29



US3312068

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-22T12:30:13', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '16bddaba-6c9c-475f-ae0b-5b45cc50d2c9'	System	22 Aug 2020 17:30:16
User entered 'No (N)'	System	22 Aug 2020 17:30:16

US3312068

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 11 Aug 2021 22:14:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-22T12:30:15', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '16bddaba-6c9c-475f-ae0b-5b45cc50d2c9'	System	22 Aug 2020 17:30:16
User entered '22 Aug 2020 12:30'	System	22 Aug 2020 17:30:16

US3312068

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:01:29

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:01:29

US3312068

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	21 Aug 2020 18:18:36
User entered 'Day 11'	System	21 Aug 2020 18:18:36

US3312068

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-23T15:31:50', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '32c342ee-a472-421d-bebc-14a992ac6d53'	System	23 Aug 2020 20:32:14
User entered 'No (N)'	System	23 Aug 2020 20:32:14

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-23T15:31:53', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '32c342ee-a472-421d-bebc-14a992ac6d53' User entered '23 Aug 2020 15:31'	System	23 Aug 2020 20:32:14
	System	23 Aug 2020 20:32:14

US3312068

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 11 Aug 2021 22:14:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 18:18:36



**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 18:18:36

US3312068

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	22 Aug 2020 17:30:02
User entered 'Day 12'	System	22 Aug 2020 17:30:02

US3312068

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-24T16:57:54', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'ad10e764-f43e-4a35-b4f2-3ba90be73092'	System	24 Aug 2020 21:57:59
User entered 'No (N)'	System	24 Aug 2020 21:57:59

US3312068

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 11 Aug 2021 22:14:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-24T16:57:56', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'ad10e764-f43e-4a35-b4f2-3ba90be73092'	System	24 Aug 2020 21:57:59
User entered '24 Aug 2020 16:57'	System	24 Aug 2020 21:57:59

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 17:30:02

US3312068

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 17:30:02

US3312068

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	23 Aug 2020 20:31:25
User entered 'Day 13'	System	23 Aug 2020 20:31:25

US3312068

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-25T12:00:23', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'cefa7363-3d96-474f-9825-4f30672384ae'	System	25 Aug 2020 17:00:27
User entered 'No (N)'	System	25 Aug 2020 17:00:27



**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(13)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-08-25T12:00:24', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'cefa7363-3d96-474f-9825-4f30672384ae'	System	25 Aug 2020 17:00:27
User entered '25 Aug 2020 12:00'	System	25 Aug 2020 17:00:27

**US3312068**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(13)**

**Generated On: 11 Aug 2021 22:14:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 20:31:25

US3312068

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 11 Aug 2021 22:14:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 20:31:25

US3312068

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 21:38:59

US3312068

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '20 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 21:38:59

US3312068

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 21:38:59

US3312068

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty.	(b) (4)	24 Sep 2020 21:38:59
	Karol Moore (b) (4)	
	(b) (4)	

US3312068

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 21:39:02



US3312068

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User entered 'I'	System	24 Sep 2020 21:39:02

US3312068

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4)	26 Oct 2020 20:31:58
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	25 Sep 2020 13:40:49
User entered 'No (N)'	Karol Moore (b) (4)	25 Sep 2020 13:40:49
	(b) (4)	

US3312068

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:40:49

US3312068

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:31:58
User entered 'Contact Not Made (CONTACT NOT MADE)'	Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:40:49

US3312068

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:31:58
User entered 'Correct as entered. Occurred during convalescent period'	Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:40:49

US3312068

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:40:58

**US3312068**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:14:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:06:10
User entered 'I'	System	25 Sep 2020 13:40:58

US3312068

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:34:35
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4)	26 Oct 2020 20:31:40
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	25 Sep 2020 13:42:17
User entered 'No (N)'	Karol Moore (b) (4)	25 Sep 2020 13:42:17
	(b) (4)	



US3312068

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:34:35
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty.	(b) (4) Karol Moore (b) (4)	25 Sep 2020 13:42:17

US3312068

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:34:35
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:31:40
User entered 'Contact Not Made (CONTACT NOT MADE)'	Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:42:17

US3312068

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:34:35
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:31:40
User entered 'Correct as entered. Occurred during convalescent period'	Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:42:17

US3312068

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:34:35
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:42:30

US3312068

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:34:35
User entered 'I'	System	25 Sep 2020 13:42:30

US3312068

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:44:30

US3312068

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4)	25 Sep 2020 13:44:30
	Karol Moore (b) (4)	
	(b) (4)	

US3312068

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:44:30



**US3312068**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:14:50**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User entered 'VISIT2'	System	25 Sep 2020 13:44:30

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	26 Oct 2020 20:30:22

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:22

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:22

**US3312068**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:14:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:22

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User entered empty.	System	26 Oct 2020 20:30:22

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:22

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:22



US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:22

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:22

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User entered empty.	System	26 Oct 2020 20:30:22

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:22

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User entered empty.	System	26 Oct 2020 20:30:22

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:22

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User entered empty.	System	26 Oct 2020 20:30:22

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:22



US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User entered empty.	System	26 Oct 2020 20:30:22

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	26 Oct 2020 20:30:22

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:22

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:22

**US3312068**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:14:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:22

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User entered empty.	System	26 Oct 2020 20:30:22

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:22

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:22



US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:22

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:22

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User entered empty.	System	26 Oct 2020 20:30:22

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:22

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User entered empty.	System	26 Oct 2020 20:30:22

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:22

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User entered empty.	System	26 Oct 2020 20:30:22

US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:22



US3312068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User entered empty.	System	26 Oct 2020 20:30:22

US3312068

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:31:06

US3312068

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:50

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:31:06

US3312068

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:14:50

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User closed query 'Per CDM: Childbearing potential noted as "yes" yet pregnancy test not completed. Kindly review and update else clarify.'" (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 02:16:22
Query 'Per CDM: Childbearing potential noted as "yes" yet pregnancy test not completed. Kindly review and update else clarify.'" answered with 'visit was not done' (Site from DM).	Kelly Moen (b) (4) (b) (4)	30 Nov 2020 18:21:02
User opened query 'Per CDM: Childbearing potential noted as "yes" yet pregnancy test not completed. Kindly review and update else clarify.'" (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 03:41:53
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 20:30:57

US3312068

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:14:50

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:57

US3312068

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:14:50

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:57

US3312068

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:14:50

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:57

US3312068

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:14:50

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:57



**US3312068**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:14:50**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:57

US3312068

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:14:50

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:57

**US3312068**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:14:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User entered empty.	System	26 Oct 2020 20:30:57

US3312068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'No (N)'	(b) (4)	25 Sep 2020 13:45:48
	Karol Moore (b) (4)	
	(b) (4)	

US3312068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:50

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'Confirmed COVID-19 (COVID)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:45:48

US3312068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:45:48

US3312068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:50

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User entered empty.	System	25 Sep 2020 13:45:48

US3312068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:45:48



US3312068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:45:48

US3312068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:50

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User entered empty.	System	25 Sep 2020 13:45:48

US3312068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:50

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4)	25 Sep 2020 13:45:48
	Karol Moore (b) (4)	
	(b) (4)	

US3312068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:50

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User entered empty.	System	25 Sep 2020 13:45:48

US3312068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:50

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User entered empty.	System	25 Sep 2020 13:45:48

US3312068

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:33

US3312068

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:33

US3312068

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:33



US3312068

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:56
User entered empty.	System	26 Oct 2020 20:30:33

US3312068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:14:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:46

**US3312068**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:14:50**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	26 Oct 2020 20:30:46

US3312068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:14:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:46

US3312068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:14:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:46

**US3312068**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:14:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User entered empty.	System	26 Oct 2020 20:30:46

**US3312068**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:14:50**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	26 Oct 2020 20:30:46

US3312068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:14:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:46



US3312068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:14:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:30:46

**US3312068**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:14:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User entered empty.	System	26 Oct 2020 20:30:46

US3312068

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:43:09

US3312068

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User entered 'I'	System	25 Sep 2020 13:43:09

US3312068

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4)	26 Oct 2020 20:32:27
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	25 Sep 2020 13:43:29
User entered 'No (N)'	Karol Moore (b) (4)	25 Sep 2020 13:43:29
	(b) (4)	

US3312068

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:43:29

US3312068

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:32:27
User entered 'Contact Not Made (CONTACT NOT MADE)'	Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:43:29

US3312068

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:32:27
User entered 'Correct as entered. Occurred during convalescent period'	Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:43:29



US3312068

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:43:38

US3312068

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User entered 'I'	System	25 Sep 2020 13:43:38

**US3312068**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:14:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:43:49

US3312068

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '24 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:43:49

US3312068

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:43:49

US3312068

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty.	(b) (4)	25 Sep 2020 13:43:49
	Karol Moore (b) (4)	
	(b) (4)	

US3312068

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:43:53

US3312068

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User entered 'I'	System	25 Sep 2020 13:43:53



**US3312068**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:14:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	05 Oct 2020 22:57:30

US3312068

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered '1 Oct 2020'	(b) (4) Monica Atwood (b) (4)	05 Oct 2020 22:57:30

**US3312068**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:14:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Monica Atwood (b) (4)	05 Oct 2020 22:57:30

US3312068

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Oct 2020 22:57:30

US3312068

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:46
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	05 Oct 2020 22:57:35

**US3312068**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:14:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User entered 'I'	System	05 Oct 2020 22:57:35

US3312068

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:45:50

US3312068

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:45:50



US3312068

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:45:50

**US3312068**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:14:50**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User entered 'VISIT3'	System	12 Oct 2020 21:45:50

US3312068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:46:12

US3312068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
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)	16 Nov 2020 15:20:02
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).	Monica Atwood (b) (4) (b) (4)	13 Nov 2020 21:38:25
User entered '08 Oct 2020' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	13 Nov 2020 21:38:18
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 18:08:33
User entered '8 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 21:46:12

**US3312068**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:14:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered '12:23'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:46:12

**US3312068**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:14:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User entered '08 Oct 2020 12:23'	System	13 Nov 2020 21:38:18
User entered '8 Oct 2020 12:23'	System	12 Oct 2020 21:46:12

US3312068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered '98.8' F	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:46:12

US3312068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:46:12



US3312068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:46:12

US3312068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered '69'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:46:12

**US3312068**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:14:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User entered 'bpm'	System	12 Oct 2020 21:46:12

US3312068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered '14'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:46:12

US3312068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User entered 'breaths/min'	System	12 Oct 2020 21:46:12

US3312068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered '115'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:46:12

US3312068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User entered 'mmHg'	System	12 Oct 2020 21:46:12

US3312068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered '75'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:46:12



US3312068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User entered 'mmHg'	System	12 Oct 2020 21:46:12

US3312068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20

**US3312068**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:14:50**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20

US3312068

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:46:20

US3312068

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:50

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:46:20

US3312068

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:46:31

US3312068

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:46:31

US3312068

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered '12:32'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:46:31



**US3312068**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:14:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User entered '8 Oct 2020 12:32'	System	12 Oct 2020 21:46:31

US3312068

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:46:34

**US3312068**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:14:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User entered 'I'	System	12 Oct 2020 21:46:34

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 64'	System	13 Aug 2020 18:30:18

US3312068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-10-13T00:01:18', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '381aebc1-fd25-4686-8f65-0559bf3188f0'	System	13 Oct 2020 05:01:37
User entered 'No (N)'	System	13 Oct 2020 05:01:37

US3312068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-10-13T00:01:26', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '381aebc1-fd25-4686-8f65-0559bf3188f0'	System	13 Oct 2020 05:01:37
User entered 'No (N)'	System	13 Oct 2020 05:01:37

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-10-13T00:01:30', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '381aebc1-fd25-4686-8f65-0559bf3188f0' User entered '13 Oct 2020 00:01:30'	System	13 Oct 2020 05:01:37
	System	13 Oct 2020 05:01:37

US3312068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 18:30:18



US3312068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 18:30:18

US3312068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 71'	System	13 Aug 2020 18:30:18

US3312068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-10-21T12:16:54', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '34cc2457-380b-4594-8465-7cc96b1728fc' User entered 'No (N)'	System	21 Oct 2020 17:17:00
	System	21 Oct 2020 17:17:00

US3312068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-10-21T12:16:56', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '34cc2457-380b-4594-8465-7cc96b1728fc' User entered 'No (N)'	System	21 Oct 2020 17:17:00
	System	21 Oct 2020 17:17:00

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-10-21T12:16:58', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '34cc2457-380b-4594-8465-7cc96b1728fc' User entered '21 Oct 2020 12:16:58'	System	21 Oct 2020 17:17:00
	System	21 Oct 2020 17:17:00

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 18:30:18

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 18:30:18

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 78'	System	13 Aug 2020 18:30:18



US3312068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-10-27T00:24:54', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '3f41e115-6977-4390-bdcf-17a3fac78c26'	System	27 Oct 2020 05:25:04
User entered 'No (N)'	System	27 Oct 2020 05:25:04

US3312068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-10-27T00:24:59', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '3f41e115-6977-4390-bdcf-17a3fac78c26'	System	27 Oct 2020 05:25:04
User entered 'No (N)'	System	27 Oct 2020 05:25:04

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-10-27T00:25:01', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '3f41e115-6977-4390-bdcf-17a3fac78c26' User entered '27 Oct 2020 00:25:01'	System	27 Oct 2020 05:25:04
	System	27 Oct 2020 05:25:04

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 18:30:18

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 18:30:18

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 92'	System	13 Aug 2020 18:30:18

US3312068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-11-10T00:01:19', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '98c17392-b762-4e2b-8a16-97aaefa51996'	System	10 Nov 2020 06:01:30
User entered 'No (N)'	System	10 Nov 2020 06:01:30

US3312068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-11-10T00:01:21', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '98c17392-b762-4e2b-8a16-97aaefa51996'	System	10 Nov 2020 06:01:30
User entered 'No (N)'	System	10 Nov 2020 06:01:30



**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-11-10T00:01:22', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '98c17392-b762-4e2b-8a16-97aaefa51996' User entered '10 Nov 2020 00:01:22'	System	10 Nov 2020 06:01:30
	System	10 Nov 2020 06:01:30

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 18:30:18

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 18:30:18

US3312068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered 'Day 99'	System	13 Aug 2020 18:30:18

US3312068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-11-17T00:13:03', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'ffdef765-6696-40d6-85c4-98761dcbb16e'	System	17 Nov 2020 06:13:09
User entered 'No (N)'	System	17 Nov 2020 06:13:09

US3312068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-11-17T00:13:04', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'ffdef765-6696-40d6-85c4-98761dcbb16e'	System	17 Nov 2020 06:13:09
User entered 'No (N)'	System	17 Nov 2020 06:13:09

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-11-17T00:13:06', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'ffdef765-6696-40d6-85c4-98761dcbb16e' User entered '17 Nov 2020 00:13:06'	System	17 Nov 2020 06:13:09
	System	17 Nov 2020 06:13:09

US3312068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 18:30:18



**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:17
Data entry locked.	System	13 Aug 2020 18:30:18
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 18:30:18

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 06:23:00

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 06:23:00

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-12-01T12:27:03', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '88d9a8b4-4a59-4f47-8868-47219a431249' User entered 'No (N)'	System	01 Dec 2020 18:27:10
	System	01 Dec 2020 18:27:10

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Have you been exposed to someone with 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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-12-01T12:27:04', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '88d9a8b4-4a59-4f47-8868-47219a431249'	System	01 Dec 2020 18:27:10
User entered 'No (N)'	System	01 Dec 2020 18:27:10

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-12-01T12:27:05', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '88d9a8b4-4a59-4f47-8868-47219a431249' User entered '01 Dec 2020 12:27:05'	System	01 Dec 2020 18:27:10
	System	01 Dec 2020 18:27:10



**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 06:23:00

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-12-05T00:01:14', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'e86390e3-0095-4470-ba07-7fa6e08fcd1a' User entered 'No (N)'	System	05 Dec 2020 06:01:25
	System	05 Dec 2020 06:01:25

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Have you been exposed to someone with 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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-12-05T00:01:15', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'e86390e3-0095-4470-ba07-7fa6e08fcd1a' User entered 'No (N)'	System	05 Dec 2020 06:01:25
	System	05 Dec 2020 06:01:25

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-12-05T00:01:17', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'e86390e3-0095-4470-ba07-7fa6e08fcd1a' User entered '05 Dec 2020 00:01:17'	System	05 Dec 2020 06:01:25
	System	05 Dec 2020 06:01:25

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 06:23:00



**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 06:23:00

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-12-12T00:01:16', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '25c74752-49aa-4da2-91d2-cebea214eb49' User entered 'No (N)'	System	12 Dec 2020 06:01:30
	System	12 Dec 2020 06:01:30

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Have you been exposed to someone with 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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-12-12T00:01:17', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '25c74752-49aa-4da2-91d2-cebea214eb49' User entered 'No (N)'	System	12 Dec 2020 06:01:30
	System	12 Dec 2020 06:01:30

**US3312068**

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

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**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-12-12T00:01:21', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '25c74752-49aa-4da2-91d2-cebea214eb49' User entered '12 Dec 2020 00:01:21'	System	12 Dec 2020 06:01:30
	System	12 Dec 2020 06:01:30

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 06:23:00

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-12-21T16:27:22', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '3ef9f717-c234-426b-82cf-8dd396217ed1'	System	21 Dec 2020 22:27:28
User entered 'No (N)'	System	21 Dec 2020 22:27:28



**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Have you been exposed to someone with 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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-12-21T16:27:24', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '3ef9f717-c234-426b-82cf-8dd396217ed1'	System	21 Dec 2020 22:27:28
User entered 'No (N)'	System	21 Dec 2020 22:27:28

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-12-21T16:27:26', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '3ef9f717-c234-426b-82cf-8dd396217ed1' User entered '21 Dec 2020 16:27:26'	System	21 Dec 2020 22:27:28
	System	21 Dec 2020 22:27:28

**US3312068**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-12-29T11:57:54', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '0a82d42b-c8fc-46fa-87e2-0fbdc00e1bb' User entered 'No (N)'	System	29 Dec 2020 17:58:00
	System	29 Dec 2020 17:58:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Have you been exposed to someone with 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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-12-29T11:57:55', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '0a82d42b-c8fc-46fa-87e2-0fbdc00e1bb' User entered 'No (N)'	System	29 Dec 2020 17:58:00
	System	29 Dec 2020 17:58:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2020-12-29T11:57:57', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '0a82d42b-c8fc-46fa-87e2-0fbdc00e1bb' User entered '29 Dec 2020 11:57:57'	System	29 Dec 2020 17:58:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-01-02T00:28:31', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b35ccc82-37c3-4995-ba74-27af7a8e144f' User entered 'No (N)'	System	02 Jan 2021 06:28:38
	System	02 Jan 2021 06:28:38

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

Have you been exposed to someone with 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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-01-02T00:28:32', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b35ccc82-37c3-4995-ba74-27af7a8e144f' User entered 'No (N)'	System	02 Jan 2021 06:28:38
	System	02 Jan 2021 06:28:38

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-01-02T00:28:34', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b35ccc82-37c3-4995-ba74-27af7a8e144f' User entered '02 Jan 2021 00:28:34'	System	02 Jan 2021 06:28:38
	System	02 Jan 2021 06:28:38

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-01-10T20:03:45', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '15a81855-3a69-45d1-b423-765ab06eafd4'	System	11 Jan 2021 02:03:50
User entered 'No (N)'	System	11 Jan 2021 02:03:50

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Have you been exposed to someone with 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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-01-10T20:03:46', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '15a81855-3a69-45d1-b423-765ab06eafd4'	System	11 Jan 2021 02:03:50
User entered 'No (N)'	System	11 Jan 2021 02:03:50

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-01-10T20:03:48', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '15a81855-3a69-45d1-b423-765ab06eafd4' User entered '10 Jan 2021 20:03:48'	System	11 Jan 2021 02:03:50
	System	11 Jan 2021 02:03:50

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-01-18T13:17:09', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b7db17c4-9fbf-46a5-8ac3-56a6ce29e863'	System	18 Jan 2021 19:17:14
User entered 'No (N)'	System	18 Jan 2021 19:17:14



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Have you been exposed to someone with 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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-01-18T13:17:10', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b7db17c4-9fbf-46a5-8ac3-56a6ce29e863'	System	18 Jan 2021 19:17:14
User entered 'No (N)'	System	18 Jan 2021 19:17:14

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-01-18T13:17:12', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'b7db17c4-9fbf-46a5-8ac3-56a6ce29e863' User entered '18 Jan 2021 13:17:12'	System	18 Jan 2021 19:17:14
	System	18 Jan 2021 19:17:14

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-01-25T15:25:21', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'd125ecbd-583f-4f2b-84e1-a31a647c4e1a' User entered 'No (N)'	System	25 Jan 2021 21:25:28
	System	25 Jan 2021 21:25:28

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Have you been exposed to someone with 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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-01-25T15:25:23', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'd125ecbd-583f-4f2b-84e1-a31a647c4e1a' User entered 'No (N)'	System	25 Jan 2021 21:25:28
	System	25 Jan 2021 21:25:28

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-01-25T15:25:25', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'd125ecbd-583f-4f2b-84e1-a31a647c4e1a' User entered '25 Jan 2021 15:25:25'	System	25 Jan 2021 21:25:28
	System	25 Jan 2021 21:25:28



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-02-03T07:24:01', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '07ad02bb-1b40-4fd6-8e45-54f1c01a6c60'	System	03 Feb 2021 13:24:07
User entered 'No (N)'	System	03 Feb 2021 13:24:07

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Have you been exposed to someone with 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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-02-03T07:24:02', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '07ad02bb-1b40-4fd6-8e45-54f1c01a6c60'	System	03 Feb 2021 13:24:07
User entered 'No (N)'	System	03 Feb 2021 13:24:07

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-02-03T07:24:04', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '07ad02bb-1b40-4fd6-8e45-54f1c01a6c60' User entered '03 Feb 2021 07:24:04'	System	03 Feb 2021 13:24:07
	System	03 Feb 2021 13:24:07

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-02-08T14:15:16', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '6fc94a30-bc21-4af2-82b2-8490fee5a5de' User entered 'No (N)'	System	08 Feb 2021 20:15:21
	System	08 Feb 2021 20:15:21

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

Have you been exposed to someone with 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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-02-08T14:15:17', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '6fc94a30-bc21-4af2-82b2-8490fee5a5de'	System	08 Feb 2021 20:15:21
User entered 'No (N)'	System	08 Feb 2021 20:15:21

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-02-08T14:15:19', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '6fc94a30-bc21-4af2-82b2-8490fee5a5de' User entered '08 Feb 2021 14:15:19'	System	08 Feb 2021 20:15:21
	System	08 Feb 2021 20:15:21

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-02-15T13:19:06', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'ec247cbc-ccb4-480a-895c-4faa4badbada' User entered 'No (N)'	System	15 Feb 2021 19:19:14
	System	15 Feb 2021 19:19:14



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Have you been exposed to someone with 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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-02-15T13:19:08', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'ec247cbc-ccb4-480a-895c-4faa4badbada' User entered 'No (N)'	System	15 Feb 2021 19:19:14
	System	15 Feb 2021 19:19:14

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-02-15T13:19:09', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'ec247cbc-ccb4-480a-895c-4faa4badbada' User entered '15 Feb 2021 13:19:09'	System	15 Feb 2021 19:19:14
	System	15 Feb 2021 19:19:14

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-02-20T00:01:27', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '4ee98665-0be5-4978-98c2-4fd4132b787c' User entered 'No (N)'	System	20 Feb 2021 06:02:15
	System	20 Feb 2021 06:02:15

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

Have you been exposed to someone with 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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-02-20T00:01:28', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '4ee98665-0be5-4978-98c2-4fd4132b787c' User entered 'No (N)'	System	20 Feb 2021 06:02:15
	System	20 Feb 2021 06:02:15

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-02-20T00:01:30', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '4ee98665-0be5-4978-98c2-4fd4132b787c' User entered '20 Feb 2021 00:01:30'	System	20 Feb 2021 06:02:15
	System	20 Feb 2021 06:02:15



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-03-02T17:17:22-06:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'e9bf4ed7-4dbe-40ed-8172-9eb290dcba00'	System	02 Mar 2021 23:18:27
User entered 'No (N)'	System	02 Mar 2021 23:18:27

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

Have you been exposed to someone with 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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-03-02T17:17:24-06:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'e9bf4ed7-4dbe-40ed-8172-9eb290dcba00'	System	02 Mar 2021 23:18:27
User entered 'No (N)'	System	02 Mar 2021 23:18:27

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-03-02T17:17:26-06:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'e9bf4ed7-4dbe-40ed-8172-9eb290dcba00'	System	02 Mar 2021 23:18:27
User entered '02 Mar 2021 17:17:26'	System	02 Mar 2021 23:18:27

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-03-09T10:12:16-06:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'e2801e76-7af8-4c55-8af4-5d949a06a2d5'	System	09 Mar 2021 16:12:31
User entered 'No (N)'	System	09 Mar 2021 16:12:31

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

Have you been exposed to someone with 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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-03-09T10:12:19-06:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'e2801e76-7af8-4c55-8af4-5d949a06a2d5'	System	09 Mar 2021 16:12:31
User entered 'No (N)'	System	09 Mar 2021 16:12:31

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-03-09T10:12:21-06:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'e2801e76-7af8-4c55-8af4-5d949a06a2d5' User entered '09 Mar 2021 10:12:21'	System	09 Mar 2021 16:12:31
	System	09 Mar 2021 16:12:31

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-03-13T17:22:50-06:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'c62d9f82-10f8-455b-8bc7-c77a0d74894a'	System	13 Mar 2021 23:22:59
User entered 'No (N)'	System	13 Mar 2021 23:22:59



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Have you been exposed to someone with 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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-03-13T17:22:52-06:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'c62d9f82-10f8-455b-8bc7-c77a0d74894a'	System	13 Mar 2021 23:22:59
User entered 'No (N)'	System	13 Mar 2021 23:22:59

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-03-13T17:22:54-06:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'c62d9f82-10f8-455b-8bc7-c77a0d74894a' User entered '13 Mar 2021 17:22:54'	System	13 Mar 2021 23:22:59
	System	13 Mar 2021 23:22:59

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-03-20T00:53:05-04:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '5848fd38-68b7-4fa5-9b3a-c6a9c9333af4'	System	20 Mar 2021 04:53:11
User entered 'No (N)'	System	20 Mar 2021 04:53:11

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Have you been exposed to someone with 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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-03-20T00:53:07-04:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '5848fd38-68b7-4fa5-9b3a-c6a9c9333af4'	System	20 Mar 2021 04:53:11
User entered 'No (N)'	System	20 Mar 2021 04:53:11

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-03-20T00:53:09-04:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '5848fd38-68b7-4fa5-9b3a-c6a9c9333af4' User entered '20 Mar 2021 00:53:09'	System	20 Mar 2021 04:53:11
	System	20 Mar 2021 04:53:11



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-03-27T00:17:27-05:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '411aecd2-aca4-4b5b-9620-32bda500c8a3'	System	27 Mar 2021 05:17:38
User entered 'No (N)'	System	27 Mar 2021 05:17:38

US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

Have you been exposed to someone with 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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-03-27T00:17:29-05:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '411aecd2-aca4-4b5b-9620-32bda500c8a3'	System	27 Mar 2021 05:17:38
User entered 'No (N)'	System	27 Mar 2021 05:17:38

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-03-27T00:17:30-05:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '411aecd2-aca4-4b5b-9620-32bda500c8a3' User entered '27 Mar 2021 00:17:30'	System	27 Mar 2021 05:17:38
	System	27 Mar 2021 05:17:38

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-04-05T12:03:45-05:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '3cf0f76a-581d-4e6b-ae5a-6be3862682ca' User entered 'No (N)'	System	12 Apr 2021 16:12:55
	System	12 Apr 2021 16:12:55

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Have you been exposed to someone with 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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-04-05T12:03:47-05:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '3cf0f76a-581d-4e6b-ae5a-6be3862682ca'	System	12 Apr 2021 16:12:55
User entered 'No (N)'	System	12 Apr 2021 16:12:55

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-04-05T12:03:49-05:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '3cf0f76a-581d-4e6b-ae5a-6be3862682ca' User entered '05 Apr 2021 12:03:49'	System	12 Apr 2021 16:12:55
	System	12 Apr 2021 16:12:55

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-04-12T11:05:33-05:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '1559198e-0fcd-4e3b-9696-511333e6c217' User entered 'No (N)'	System	17 Apr 2021 15:19:02
	System	17 Apr 2021 15:19:02



US3312068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:50

Have you been exposed to someone with 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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-04-12T11:05:34-05:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '1559198e-0fcd-4e3b-9696-511333e6c217'	System	17 Apr 2021 15:19:02
User entered 'No (N)'	System	17 Apr 2021 15:19:02

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-04-12T11:05:36-05:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '1559198e-0fcd-4e3b-9696-511333e6c217'	System	17 Apr 2021 15:19:02
User entered '12 Apr 2021 11:05:36'	System	17 Apr 2021 15:19:02

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-04-17T10:18:58-05:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'a1ac6e66-ec4b-42ba-94dd-0a9ad70f76d6'	System	24 Apr 2021 05:02:19
User entered 'No (N)'	System	24 Apr 2021 05:02:19

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Have you been exposed to someone with 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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-04-17T10:18:59-05:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'a1ac6e66-ec4b-42ba-94dd-0a9ad70f76d6'	System	24 Apr 2021 05:02:19
User entered 'No (N)'	System	24 Apr 2021 05:02:19

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-04-17T10:19:01-05:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'a1ac6e66-ec4b-42ba-94dd-0a9ad70f76d6'	System	24 Apr 2021 05:02:19
User entered '17 Apr 2021 10:19:01'	System	24 Apr 2021 05:02:19



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-04-24T00:02:15-05:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'f5991d30-ff7d-4cc8-8f11-597ae6abcf34'	System	24 Apr 2021 05:02:23
User entered 'No (N)'	System	24 Apr 2021 05:02:23

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Have you been exposed to someone with 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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-04-24T00:02:16-05:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'f5991d30-ff7d-4cc8-8f11-597ae6abcf34'	System	24 Apr 2021 05:02:23
User entered 'No (N)'	System	24 Apr 2021 05:02:23

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-04-24T00:02:17-05:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'f5991d30-ff7d-4cc8-8f11-597ae6abcf34' User entered '24 Apr 2021 00:02:17'	System	24 Apr 2021 05:02:23
	System	24 Apr 2021 05:02:23

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-05-01T11:57:18-05:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '912b7393-d16e-41a5-ae14-e9b4e14e41e0' User entered 'No (N)'	System	01 May 2021 16:57:25
	System	01 May 2021 16:57:25

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Have you been exposed to someone with 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 (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-05-01T11:57:20-05:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '912b7393-d16e-41a5-ae14-e9b4e14e41e0'	System	01 May 2021 16:57:25
User entered 'No (N)'	System	01 May 2021 16:57:25

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-05-01T11:57:21-05:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: '912b7393-d16e-41a5-ae14-e9b4e14e41e0' User entered '01 May 2021 11:57:21'	System	01 May 2021 16:57:25
	System	01 May 2021 16:57:25

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 06:23:00



**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 06:23:00

**US3312068**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:14:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:23:00
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 06:23:00

US3312068

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:14:50

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:44:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-03-02T17:17:33-06:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'c98a6e10-7be5-4c09-bfa2-275c4221a860'	System	02 Mar 2021 23:18:37
User entered 'No (N)'	System	02 Mar 2021 23:18:37

**US3312068**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:14:50**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:44:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (869FCD28-CCB2-4A39-8FCC-0F0E85A5E94A)', Time: '2021-03-02T17:17:36-06:00', User OID: 'PatientReportedOutcome (US3312068)', ODM File OID: 'c98a6e10-7be5-4c09-bfa2-275c4221a860'	System	02 Mar 2021 23:18:37
User entered '02 Mar 2021 17:17:36'	System	02 Mar 2021 23:18:37

**US3312068**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:14:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:58:03

**US3312068**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:14:50**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '06 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:58:03

US3312068

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:58:03

US3312068

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:58:03



US3312068

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:58:50

**US3312068**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:14:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:20
User entered 'I'	System	16 Nov 2020 21:58:50

**US3312068**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:14:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:41:39

**US3312068**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:14:50**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '09 Dec 2020'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:41:39

**US3312068**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:14:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:41:39

US3312068

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:41:39

US3312068

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:41:43

**US3312068**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:14:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User entered 'I'	System	10 Dec 2020 16:41:43



**US3312068**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:14:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:13:50

US3312068

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '06 Jan 2021'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:13:50

US3312068

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:13:50

US3312068

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:13:50

US3312068

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:14:05

**US3312068**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:14:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User entered 'I'	System	07 Jan 2021 15:14:05

**US3312068**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:14:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:45:55

**US3312068**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:14:50**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '05 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:45:55



**US3312068**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:14:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:45:55

US3312068

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:45:55

US3312068

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:45:42

**US3312068**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:14:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User entered '1'	System	12 Feb 2021 15:45:42

US3312068

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:11:51

**US3312068**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:14:50**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:11:51

US3312068

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:50

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:11:51

**US3312068**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:14:50**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User entered 'VISIT4'	System	15 Mar 2021 13:11:51



US3312068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:18:47

US3312068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:18:47

**US3312068**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:14:50**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:18:47

US3312068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User entered empty.	System	29 Mar 2021 18:18:47

US3312068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:18:47

US3312068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:18:47

US3312068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:18:47

US3312068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:18:47



US3312068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User entered empty.	System	29 Mar 2021 18:18:47

US3312068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:18:47

US3312068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User entered empty.	System	29 Mar 2021 18:18:47

US3312068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:18:47

US3312068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User entered empty.	System	29 Mar 2021 18:18:47

US3312068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:18:47

US3312068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User entered empty.	System	29 Mar 2021 18:18:47

US3312068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24



**US3312068**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:14:50**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24

US3312068

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:11:57

US3312068

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:11:57

US3312068

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:12:11

US3312068

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:12:11

US3312068

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '13:36'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:12:11

US3312068

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User entered '12 Mar 2021 13:36'	System	15 Mar 2021 13:12:11

US3312068

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:12:14



**US3312068**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:14:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:24
User entered 'I'	System	15 Mar 2021 13:12:14

**US3312068**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:14:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:24:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 19:25:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:37:42

**US3312068**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:14:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:24:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 19:25:20
User entered '06 Apr 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:37:42

US3312068

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:24:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 19:25:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:37:42

US3312068

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:50

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:24:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 19:25:20
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:37:42

US3312068

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:24:36
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 19:25:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:37:46

**US3312068**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:14:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:24:36
User entered 'I'	System	06 Apr 2021 18:37:46

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:14:50

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:02:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '25 Aug 2020' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 19:58:59
User entered '24 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 00:37:34



US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:14:50

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:02:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '10:00'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:37:34

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:14:50

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:32
User entered '25 Aug 2020 10:00'	System	21 Oct 2020 19:58:59
User entered '24 Aug 2020 10:00'	System	27 Aug 2020 00:37:34

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:14:50

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:02:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Safety Call (Safety Call)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:37:34

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:14:50

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:02:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:37:34

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:42:53

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '17 Aug 2020' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:51:43
User entered '25 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 00:42:53

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:42:53

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:31:08
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	26 Oct 2020 19:51:43
User entered '98'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:42:53



US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User entered '%'	System	18 Dec 2020 16:31:08
User entered empty.	System	26 Oct 2020 19:51:43
User entered '%'	System	27 Aug 2020 00:42:53

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:31:08
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	26 Oct 2020 19:51:43
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:42:53

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:42:53

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:51:43
User entered 'Mild (Mild)'	(b) (4), (b) (6)	27 Aug 2020 00:42:53

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:51:43
User entered 'Mild (Mild)'	(b) (4), (b) (6)	27 Aug 2020 00:42:53

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:42:53

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 19:53:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 19:51:43
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 00:42:53

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:42:53



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:42:53

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:51:43
User entered 'None (None)'	Karol Moore (b) (4)	27 Aug 2020 00:42:53
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:42:53

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:42:53

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:42:53

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:42:53

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:42:53

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:42:53



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:42:53

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:42:53

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:44:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '18 Aug 2020' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:53:24
User entered '26 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 00:44:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:44:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:31:08
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	26 Oct 2020 19:53:24
User entered '97'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:44:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User entered '%'	System	18 Dec 2020 16:31:08
User entered empty.	System	26 Oct 2020 19:53:24
User entered '%'	System	27 Aug 2020 00:44:25

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:31:08
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	26 Oct 2020 19:53:24
User entered '97.5' F	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:44:25



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:44:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:53:24
User entered 'Mild (Mild)'	(b) (4), (b) (6)	27 Aug 2020 00:44:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:53:24
User entered 'Mild (Mild)'	(b) (4), (b) (6)	27 Aug 2020 00:44:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:44:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:53:24
User entered 'None (None)'	Karol Moore (b) (4)	27 Aug 2020 00:44:25
	(b) (4)	
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:53:24
User entered 'None (None)'	Karol Moore (b) (4)	27 Aug 2020 00:44:25
	(b) (4)	
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:53:24
User entered 'None (None)'	Karol Moore (b) (4)	27 Aug 2020 00:44:25
	(b) (4)	
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:53:24
User entered 'None (None)'	Karol Moore (b) (4)	27 Aug 2020 00:44:25
	(b) (4)	
	(b) (4), (b) (6)	



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:44:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:44:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:44:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:44:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:44:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:44:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:44:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:44:25



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Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:25:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '19 Aug 2020' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:55:53
User entered '27 Aug 2020'	(b) (4), (b) (6)	02 Sep 2020 01:25:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:25:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:31:08
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	26 Oct 2020 19:55:53
User entered '98'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:25:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User entered '%'	System	18 Dec 2020 16:31:08
User entered empty.	System	26 Oct 2020 19:55:53
User entered '%'	System	02 Sep 2020 01:25:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:31:08
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	26 Oct 2020 19:55:53
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:25:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:25:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:55:53
User entered 'Mild (Mild)'	(b) (4), (b) (6)	02 Sep 2020 01:25:21



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:55:53
User entered 'Mild (Mild)'	(b) (4), (b) (6)	02 Sep 2020 01:25:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:25:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:55:53
User entered 'None (None)'	Karol Moore (b) (4)	02 Sep 2020 01:25:21
	(b) (4)	
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:55:53
User entered 'None (None)'	Karol Moore (b) (4)	02 Sep 2020 01:25:21
	(b) (4)	
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:55:53
User entered 'None (None)'	Karol Moore (b) (4)	02 Sep 2020 01:25:21
	(b) (4)	
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:55:53
User entered 'None (None)'	Karol Moore (b) (4)	02 Sep 2020 01:25:21
	(b) (4)	
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:25:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:25:21



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:25:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:25:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:55:53
User entered 'None (None)'	Karol Moore (b) (4)	02 Sep 2020 01:25:21
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:55:53
User entered 'None (None)'	Karol Moore (b) (4)	02 Sep 2020 01:25:21
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:25:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:25:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:26:39

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '20 Aug 2020' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:56:49
User entered '28 Aug 2020'	(b) (4), (b) (6)	02 Sep 2020 01:26:39



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:26:39

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:31:08
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	26 Oct 2020 19:56:49
User entered '98'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:26:39

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User entered '%'	System	18 Dec 2020 16:31:08
User entered empty.	System	26 Oct 2020 19:56:49
User entered '%'	System	02 Sep 2020 01:26:39

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:31:08
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	26 Oct 2020 19:56:49
User entered '96.6' F	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:26:39

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:26:39

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:56:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	02 Sep 2020 01:26:39

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:56:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	02 Sep 2020 01:26:39

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:26:39



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Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:56:49
User entered 'None (None)'	Karol Moore (b) (4)	02 Sep 2020 01:26:39
	(b) (4)	
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:56:49
User entered 'None (None)'	Karol Moore (b) (4)	02 Sep 2020 01:26:39
	(b) (4)	
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:56:49
User entered 'None (None)'	Karol Moore (b) (4)	02 Sep 2020 01:26:39
	(b) (4)	
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:56:49
User entered 'None (None)'	Karol Moore (b) (4)	02 Sep 2020 01:26:39
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:26:39

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:26:39

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:26:39

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Form: Symptom Log (4)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:26:39



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:26:39

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:26:39

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:26:39

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:26:39

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:27:58

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:58:09
User entered '29 Aug 2020'	(b) (4), (b) (6)	02 Sep 2020 01:27:58

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:27:58

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:31:08
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	26 Oct 2020 19:58:09
User entered '97'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:27:58



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User entered '%'	System	18 Dec 2020 16:31:08
User entered empty.	System	26 Oct 2020 19:58:09
User entered '%'	System	02 Sep 2020 01:27:58

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:31:08
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	26 Oct 2020 19:58:09
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:27:58

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:27:58

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:27:58

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:27:58

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:27:58

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:27:58

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:58:09
User entered 'None (None)'	Karol Moore (b) (4)	02 Sep 2020 01:27:58
	(b) (4)	
	(b) (4), (b) (6)	



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:58:09
User entered 'None (None)'	Karol Moore (b) (4)	02 Sep 2020 01:27:58
	(b) (4)	
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:58:09
User entered 'None (None)'	Karol Moore (b) (4)	02 Sep 2020 01:27:58
	(b) (4)	
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:27:58

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:27:58

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:27:58

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:27:58

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:27:58

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:27:58



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:27:58

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:27:58

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:30:08

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '22 Aug 2020' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:58:56
User entered '30 Aug 2020'	(b) (4), (b) (6)	02 Sep 2020 01:30:08

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:30:08

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:31:08
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	26 Oct 2020 19:58:56
User entered '96'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:30:08

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User entered '%'	System	18 Dec 2020 16:31:08
User entered empty.	System	26 Oct 2020 19:58:56
User entered '%'	System	02 Sep 2020 01:30:08

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:31:08
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	26 Oct 2020 19:58:56
User entered '97.4' F	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:30:08



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:30:08

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:30:08

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:30:08

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:30:08

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:30:08

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:58:56
User entered 'None (None)'	Karol Moore (b) (4)	02 Sep 2020 01:30:08
	(b) (4)	
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:58:56
User entered 'None (None)'	Karol Moore (b) (4)	02 Sep 2020 01:30:08
	(b) (4)	
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:58:56
User entered 'None (None)'	Karol Moore (b) (4)	02 Sep 2020 01:30:08
	(b) (4)	
	(b) (4), (b) (6)	



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Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:30:08

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:30:08

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:30:08

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:30:08

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:30:08

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:30:08

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:30:08

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:30:08



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '23 Aug 2020' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:59:35
User entered '31 Aug 2020'	(b) (4), (b) (6)	02 Sep 2020 01:31:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:31:08
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	26 Oct 2020 19:59:35
User entered '99'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User entered '%'	System	18 Dec 2020 16:31:08
User entered empty.	System	26 Oct 2020 19:59:35
User entered '%'	System	02 Sep 2020 01:31:00

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:31:08
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	26 Oct 2020 19:59:35
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:00



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:00

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:00

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:00

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:59:35
User entered 'None (None)'	Karol Moore (b) (4)	02 Sep 2020 01:31:00
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:59:35
User entered 'None (None)'	Karol Moore (b) (4)	02 Sep 2020 01:31:00
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:59:35
User entered 'None (None)'	Karol Moore (b) (4)	02 Sep 2020 01:31:00
	(b) (4)	
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:00



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:00

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:00

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:00

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:49

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '24 Aug 2020' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 20:00:26
User entered '01 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 01:31:49



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:49

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:31:08
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	26 Oct 2020 20:00:26
User entered '99'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:49

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User entered '%'	System	18 Dec 2020 16:31:08
User entered empty.	System	26 Oct 2020 20:00:26
User entered '%'	System	02 Sep 2020 01:31:49

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:31:08
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	26 Oct 2020 20:00:26
User entered '97.0' F	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:49

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:49

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:49

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:49

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:49



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:49

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 20:00:26
User entered 'None (None)'	Karol Moore (b) (4)	02 Sep 2020 01:31:49
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:49

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 20:00:26
User entered 'None (None)'	Karol Moore (b) (4)	02 Sep 2020 01:31:49
	(b) (4)	
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:49

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:49

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:49

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:49



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:49

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:49

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:49

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:31:49

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Day 9 (Day 9)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:00:49

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '25 Aug 2020' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 20:02:03
User entered '02 Sep 2020'	Karol Moore (b) (4)	21 Oct 2020 20:00:49
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:00:49
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '98' reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:02:03
	(b) (4)	
User entered '100'	Karol Moore (b) (4)	21 Oct 2020 20:00:49
	(b) (4)	



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User entered '%'	System	21 Oct 2020 20:00:49

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '98.0' F reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:02:03
	(b) (4)	
User entered '98.6' F	Karol Moore (b) (4)	21 Oct 2020 20:00:49
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:00:49
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:02:03
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:00:49
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:02:03
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:00:49
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:00:49
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:00:49
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:00:49



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:00:49
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	21 Oct 2020 20:00:49
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:00:49
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:00:49

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:00:49
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:00:49
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:00:49
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:00:49
	(b) (4)	



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:00:49
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:00:49
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Day 10 (Day 10)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:02:05

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '26 Aug 2020' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 20:02:55
User entered '03 Sep 2020'	Karol Moore (b) (4)	21 Oct 2020 20:02:05
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:02:05

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '97' reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:02:55
User entered '96'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:02:05
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User entered '%'	System	21 Oct 2020 20:02:05

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '97.5' F reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:02:55
User entered '98' F	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:02:05
	(b) (4)	



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:02:05
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:02:55
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:02:05
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:02:55
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:02:05
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:02:05
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:02:05
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:02:05

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:02:05
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	21 Oct 2020 20:02:05
	Karol Moore (b) (4)	
	(b) (4)	



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:02:05

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:02:05

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:02:05
	(b) (4)	

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Form: Symptom Log (10)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:02:05

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Form: Symptom Log (10)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:02:05

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:02:05
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	21 Oct 2020 20:02:05
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:02:05



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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Day 11 (Day 11)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:02:45

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '27 Aug 2020' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 20:03:40
User entered '04 Sep 2020'	Karol Moore (b) (4)	21 Oct 2020 20:02:45
	(b) (4)	

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Form: Symptom Log (11)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:02:45

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '98'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:02:45

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User entered '%'	System	21 Oct 2020 20:02:45

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Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '98' F reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:03:40
	(b) (4)	
User entered '97.8' F	Karol Moore (b) (4)	21 Oct 2020 20:02:45
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:02:45
	(b) (4)	

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Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:03:40
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:02:45
	(b) (4)	



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Form: Symptom Log (11)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:03:40
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:02:45
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:02:45

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:02:45

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:02:45

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:02:45
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:02:45
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:02:45

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:02:45



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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:02:45
	(b) (4)	

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Form: Symptom Log (11)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:02:45

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:02:45
	(b) (4)	

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Form: Symptom Log (11)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:02:45
	(b) (4)	

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Form: Symptom Log (11)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:02:45

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:02:45
	(b) (4)	

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Form: Symptom Log (12)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Day 12 (Day 12)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:03:10

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Form: Symptom Log (12)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '28 Aug 2020' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 20:04:51
User entered '05 Sep 2020'	Karol Moore (b) (4)	21 Oct 2020 20:03:10
	(b) (4)	



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Form: Symptom Log (12)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:10
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '98' reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:04:51
User entered '99'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:10
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User entered '%'	System	21 Oct 2020 20:03:10

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '96.6' F reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:04:51
User entered '98.3' F	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:10
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:10
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:04:51
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:10
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:04:51
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:10
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:10
	(b) (4)	



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Form: Symptom Log (12)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:10
	(b) (4)	

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Form: Symptom Log (12)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:03:10

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Form: Symptom Log (12)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:10
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:10
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:10
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:10
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:10
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	21 Oct 2020 20:03:10
	Karol Moore (b) (4)	
	(b) (4)	



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:10
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:10
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:10
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:10
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Day 13 (Day 13)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:03:55

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '29 Aug 2020' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 20:06:14
User entered '06 Sep 2020'	Karol Moore (b) (4)	21 Oct 2020 20:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '97' reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:06:14
User entered '99'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:55
	(b) (4)	



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User entered '%'	System	21 Oct 2020 20:03:55

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '97.8' F	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:03:55

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:03:55

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:03:55



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:03:55

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:03:55

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	21 Oct 2020 20:03:55
	Karol Moore (b) (4)	
	(b) (4)	



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Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:03:55

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Day 14 (Day 14)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:04:24

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '30 Aug 2020' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 20:06:52
User entered '07 Sep 2020'	Karol Moore (b) (4)	21 Oct 2020 20:04:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '0'	(b) (4)	21 Oct 2020 20:04:24
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '96' reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:06:52
	(b) (4)	
User entered '98'	Karol Moore (b) (4)	21 Oct 2020 20:04:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User entered '%'	System	21 Oct 2020 20:04:24

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '97.4' F reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:06:52
	(b) (4)	
User entered '98.9' F	Karol Moore (b) (4)	21 Oct 2020 20:04:24
	(b) (4)	



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:04:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:04:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:04:24

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:04:24

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:04:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:04:24

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:04:24
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:04:24
	(b) (4)	



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:04:24
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:04:24

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:04:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:04:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:04:24
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:04:24
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:04:24
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:04:24



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Day 15 (Day 15)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:07:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '31 Aug 2020'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:07:44
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:07:44
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '99'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:07:44
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User entered '%'	System	26 Oct 2020 20:07:44

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '97.9' F	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:07:44
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:07:44
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:07:44
	(b) (4)	



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:07:44
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:07:44

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:07:44
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:07:44
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:07:44
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:07:44
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:07:44

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:07:44



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:07:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:07:44
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:07:44
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:07:44
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:07:44
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:07:44
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Day 16 (Day 16)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:08:43

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '01 Sep 2020'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:08:43
	(b) (4)	



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:08:43
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '99'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:08:43
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User entered '%'	System	26 Oct 2020 20:08:43

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '97.0' F	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:08:43
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:08:43
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:08:43
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:08:43
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:08:43



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:08:43
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:08:43

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:08:43
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:08:43
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:08:43

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:08:43

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:08:43

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:08:43



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:08:43
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:08:43

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:08:43
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:08:43

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Day 17 (Day 17)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:09:22

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '02 Sep 2020'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:09:22
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:09:22
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '100'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:09:22
	(b) (4)	



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User entered '%'	System	26 Oct 2020 20:09:22

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '96.6' F	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:09:22
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:09:22
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:09:22
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:09:22

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:09:22
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:09:22
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:09:22



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:09:22
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:09:22
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:09:22

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:09:22

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:09:22
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:09:22
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:09:22
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:09:22
	(b) (4)	



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:09:22
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:09:22
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Day 18 (Day 18)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:10:01

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '03 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:10:01

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:10:01
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '96'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:10:01

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User entered '%'	System	26 Oct 2020 20:10:01

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '98' F	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:10:01
	(b) (4)	



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:10:01
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:10:01
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:10:01

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:10:01

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:10:01
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:10:01

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:10:01
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:10:01
	(b) (4)	



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:10:01

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:10:01

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:10:01

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:10:01

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:10:01

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:10:01

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:10:01
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:10:01
	(b) (4)	



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Day 19 (Day 19)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:10:53

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User closed query 'per CDM: please confirm date for day 19, as day 18 also noted as 03 Sep 2020' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 09:31:33
Query 'per CDM: please confirm date for day 19, as day 18 also noted as 03 Sep 2020' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	19 Mar 2021 22:56:02
User entered '04 Sep 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	19 Mar 2021 22:55:52
User opened query 'per CDM: please confirm date for day 19, as day 18 also noted as 03 Sep 2020' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 07:30:30
User entered '03 Sep 2020'	Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:10:53

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:10:53
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '98'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:10:53
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User entered '%'	System	26 Oct 2020 20:10:53

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '97.8' F	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:10:53
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:10:53
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:10:53
	(b) (4)	



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:10:53

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:10:53
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:10:53
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:10:53

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:10:53
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:10:53
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:10:53

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:10:53



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:10:53

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:10:53
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:10:53
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:10:53
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:10:53

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:10:53

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Day 20 (Day 20)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:11:36

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '05 Sep 2020'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:11:36
	(b) (4)	



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:11:36
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '99'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:11:36
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User entered '%'	System	26 Oct 2020 20:11:36

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '98.3' F	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:11:36
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:11:36
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:11:36
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:11:36
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:11:36
	(b) (4)	



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:11:36
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:11:36
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:11:36
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:11:36
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:11:36

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:11:36

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:11:36
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:11:36
	(b) (4)	



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:11:36
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:11:36
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:11:36
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:11:36

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:14:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Day 21 (Day 21)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:12:11

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:14:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '06 Sep 2020'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:12:11
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:14:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:12:11
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '99'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:12:11
	(b) (4)	



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User entered '%'	System	26 Oct 2020 20:12:11

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:14:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '97.8' F	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:12:11
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:14:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:12:11
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:14:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:12:11
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:14:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:12:11
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:14:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:12:11

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:14:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:12:11
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:14:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:12:11



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:14:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:12:11
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:14:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:12:11
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:12:11

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:12:11
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:14:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:12:11

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:14:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:12:11

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:14:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:12:11
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:14:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:12:11



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:14:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:12:11
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:14:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:12:11

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:14:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Day 22 (Day 22)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:13:04

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:14:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
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 21SEP2020. Please reconcil or clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:36:58
Query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 21SEP2020. Please reconcil or clarify.' answered with 'na. per protocol "Log must be completed for 14 days or until symptoms resolve for participants that are confirmed SARs-CoV-2 positive" Day 22 is day 14 of the convalescent period' (Site from DM).	Karol Moore (b) (4) (b) (4)	10 Nov 2020 16:02:46
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 21SEP2020. Please reconcil or clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 03:09:56
User entered '07 Sep 2020'	Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:13:04

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:14:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:13:04
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '98'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:13:04
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:14:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
User entered '%'	System	26 Oct 2020 20:13:04

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:14:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '98.9' F	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:13:04
	(b) (4)	



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:14:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:13:04
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:14:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:13:04
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:14:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:13:04
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:14:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:13:04
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:14:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:13:04
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:14:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:13:04
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:14:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:13:04
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:14:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:13:04
	(b) (4)	



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Oct 2020 20:13:04

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:14:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:13:04
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:14:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:13:04
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:14:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:13:04
	(b) (4)	

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:14:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:13:04
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:14:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:13:04
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:14:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:13:04
	(b) (4)	

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:14:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	26 Oct 2020 20:13:04
	(b) (4)	



US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:14:50

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:20:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User closed query 'Per GCL LAB reconciliation: Saliva: PPD lab has a 25AUG2020 Saliva sample reported. Please confirm if the Saliva sample was also collected along with the Swab sample at this COVID-19 Assessment visit then as per CCG v 4.0 pg 28, the Saliva details will be recorded in a same date 2nd COVID-19 visit with Saliva details in COVID Diagnostic form. Or if Saliva sample was not collected on 25AUG2020 for this subject then update the Preclarus. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 13:49:46
Query 'Per GCL LAB reconciliation: Saliva: PPD lab has a 25AUG2020 Saliva sample reported. Please confirm if the Saliva sample was also collected along with the Swab sample at this COVID-19 Assessment visit then as per CCG v 4.0 pg 28, the Saliva details will be recorded in a same date 2nd COVID-19 visit with Saliva details in COVID Diagnostic form. Or if Saliva sample was not collected on 25AUG2020 for this subject then update the Preclarus. Thank you. ' answered with 'CONFIRMED SALIVA SAMPLE COLLECTED. ACCESSION NUMBER: 1F67400' (Site from DM).	Karol Moore (b) (4) (b) (4)	19 Feb 2021 18:36:31
User opened query 'Per GCL LAB reconciliation: Saliva: PPD lab has a 25AUG2020 Saliva sample reported. Please confirm if the Saliva sample was also collected along with the Swab sample at this COVID-19 Assessment visit then as per CCG v 4.0 pg 28, the Saliva details will be recorded in a same date 2nd COVID-19 visit with Saliva details in COVID Diagnostic form. Or if Saliva sample was not collected on 25AUG2020 for this subject then update the Preclarus. Thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Jan 2021 09:00:53
User entered '25 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 00:41:13

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:14:50

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:20:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:41:13

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:14:50

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:20:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
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)	08 Sep 2020 10:16:42
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 01:09:36
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 01:08:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 01:08:14
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	02 Sep 2020 01:08:14
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 01:08:14
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 00:41:13
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 00:41:13

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Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:14:50

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:20:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:41:13

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:14:50

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:20:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	27 Aug 2020 00:41:13

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:14:50

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:20:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:41:13

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:14:50

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:20:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:41:13

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Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:14:50

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:20:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:41:13



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Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:14:50

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:20:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:41:13

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Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:14:50

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:48
User entered 'I'	System	02 Sep 2020 01:08:14

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

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)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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Folder: Covid-19 Assessment 25 Aug 2020

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Generated On: 11 Aug 2021 22:14:50

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Sep 2020 01:33:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 01:33:07
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 01:33:07
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 01:32:54
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 01:32:54

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Folder: Covid-19 Assessment 25 Aug 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54



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Generated On: 11 Aug 2021 22:14:50

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

US3312068

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User closed query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia and update accordingly as it appears responses are missing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 06:02:32
Query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia and update accordingly as it appears responses are missing.' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	19 Feb 2021 18:37:44
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4) (b) (4)	19 Feb 2021 18:37:29
User opened query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia and update accordingly as it appears responses are missing.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 19:37:06
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 01:32:54

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Generated On: 11 Aug 2021 22:14:50

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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Folder: Covid-19 Assessment 25 Aug 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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[Evidence of Shock Requires  
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54



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Folder: Covid-19 Assessment 25 Aug 2020

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty; reason for change Data Entry Error	(b) (4)	19 Feb 2021 18:37:29
User entered 'No (N)'	Karol Moore (b) (4)	02 Sep 2020 01:32:54
	(b) (4)	
	(b) (4), (b) (6)	

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54



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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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Folder: Covid-19 Assessment 25 Aug 2020

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:50

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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Folder: Covid-19 Assessment 25 Aug 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:32:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:14:50

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:31
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 20:14:20
User entered 'Yes (Y)'	Karol Moore (b) (4)	21 Oct 2020 20:04:54
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:14:50

[Visit](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.27,29AUG2020 is recorded under Illness Visit Day 3,5 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. ' canceled (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 09:58:37
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.27,29AUG2020 is recorded under Illness Visit Day 3,5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 09:55:41
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	10 Sep 2020 20:20:00

**US3312068**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:14:50**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:27:21
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 20:20:00



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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:14:50

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:27:21
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User closed query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 13:51:28
Query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' answered with 'CONFIRMED SHIPPED. ACCESSION NUMBER: 1F67400' (Site from DM).	Karol Moore (b) (4) (b) (4)	19 Feb 2021 18:39:26
User opened query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	10 Jan 2021 09:01:46
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for the response, however please confirm if sample was collected on 25AUG2020 if yes, please update the sample details in Saliva log as its reported in PPD central lab.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 09:33:03
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for the response, however please confirm if sample was collected on 25AUG2020 if yes, please update the sample details in Saliva log as its reported in PPD central lab.' answered with 'DAY 3 WAS COLLECTED ON 27AUG2020. ILLNESS DAY 1 WAS COLLECTED ON 25AUG2020' (Site from DM).	Karol Moore (b) (4) (b) (4)	17 Dec 2020 16:02:43

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:14:50

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27,28AUG2020 and 14SEP2020 is recorded under Illness Visit Day 3,5,21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 10:09:01
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for the response, however please confirm if sample was collected on 25AUG2020 if yes, please update the sample details in Saliva log as its reported in PPD central lab.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 10:08:58
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25AUG2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 10:08:58
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27,28AUG2020 and 14SEP2020 is recorded under Illness Visit Day 3,5,21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'CONFIRMED SHIPPED' (Site from DM).	Karol Moore (b) (4) (b) (4)	13 Dec 2020 21:38:10
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25AUG2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'CONFIRMED COLLECTED' (Site from DM).	Karol Moore (b) (4) (b) (4)	13 Dec 2020 21:38:03

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:14:50

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25AUG2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 04:31:49
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27,28AUG2020 and 14SEP2020 is recorded under Illness Visit Day 3,5,21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 10:29:30
User entered '27 Aug 2020'	(b) (4), (b) (6)	10 Sep 2020 20:20:00

**US3312068**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:14:50**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	10 Sep 2020 20:20:00

**US3312068**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:14:50**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:27:21
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 20:20:00

US3312068

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:14:50

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:27:21
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User closed query 'Per GCL Lab Reconciliation: Saliva: Per previous query response on the Log line # 1, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 13:53:17
Query 'Per GCL Lab Reconciliation: Saliva: Per previous query response on the Log line # 1, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' answered with 'CONFIRMED SHIPPED. ACCESSION NUMBER: 1F67400' (Site from DM).	Karol Moore (b) (4) (b) (4)	19 Feb 2021 18:39:57
User opened query 'Per GCL Lab Reconciliation: Saliva: Per previous query response on the Log line # 1, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	10 Jan 2021 09:02:24
User closed query 'Per GCL L ab Recon: GCL has Saliva Day 5 date as 25AUG2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 06:55:47
Query 'Per GCL L ab Recon: GCL has Saliva Day 5 date as 25AUG2020. Please reconcile or clarify.' answered with 'correct as entered, day 5 is 29aug2020' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 20:28:16
User opened query 'Per GCL L ab Recon: GCL has Saliva Day 5 date as 25AUG2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 10:37:15
User entered '29 Aug 2020'	(b) (4), (b) (6)	10 Sep 2020 20:20:00

US3312068

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:14:50

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	10 Sep 2020 20:20:00

**US3312068**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:14:50**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:27:21
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 20:20:00



**US3312068**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:14:50**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:27:21
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 20:20:00

**US3312068**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:14:50**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	10 Sep 2020 20:20:00

**US3312068**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:14:50**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:27:21
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 20:20:00

**US3312068**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:14:50**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:27:21
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '02 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 20:20:00

**US3312068**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 22:14:50**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	10 Sep 2020 20:20:00

**US3312068**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 22:14:50**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:27:21
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 20:20:00

US3312068

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:14:50

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:27:21
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User closed query 'Per GCL Reconciliation: Saliva sample collected on 07SEP2020 is labelled under "Visit 01 Baseline Month 0" in Viracor data and in GCL it is labelled under "Illness D3-D21". Please verify the correct visit for sample collected on this date. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 10:19:51
Query 'Per GCL Reconciliation: Saliva sample collected on 07SEP2020 is labelled under "Visit 01 Baseline Month 0" in Viracor data and in GCL it is labelled under "Illness D3-D21". Please verify the correct visit for sample collected on this date. ' answered with 'Confirmed. correct as entered. 07SEP2020 is Illness D14 sample' (Site from DM).	Karol Moore (b) (4) (b) (4)	10 Nov 2020 16:04:28
User opened query 'Per GCL Reconciliation: Saliva sample collected on 07SEP2020 is labelled under "Visit 01 Baseline Month 0" in Viracor data and in GCL it is labelled under "Illness D3-D21". Please verify the correct visit for sample collected on this date. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:44:27
User entered '07 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 20:20:00

US3312068

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:14:50

[Visit](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.14SEP2020 is recorded under Illness Visit Day 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. ' canceled (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 09:58:49
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.14SEP2020 is recorded under Illness Visit Day 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. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 09:56:06
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	10 Sep 2020 20:20:00



US3312068

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:14:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:27:21
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Sep 2020 19:50:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 19:50:31
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 19:50:31
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 20:20:00
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 20:20:00

US3312068

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:14:50

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:27:21
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User closed query 'Per GCL L ab Recon: GCL has Saliva Day 21 date as 17SEP2020. Please reconcile or clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 06:55:33
Query 'Per GCL L ab Recon: GCL has Saliva Day 21 date as 17SEP2020. Please reconcile or clarify.' answered with 'correct as entered, 09/14/20 is day 21' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 20:29:43
User opened query 'Per GCL L ab Recon: GCL has Saliva Day 21 date as 17SEP2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 10:36:38
User entered '14 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 19:50:59
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 20:20:00

**US3312068**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:14:50**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	10 Sep 2020 20:20:00

US3312068

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:14:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:27:21
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Oct 2020 20:23:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 20:23:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 20:23:33
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Sep 2020 20:20:00
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 20:20:00

US3312068

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:14:50

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:27:21
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User closed query 'Per GCL Reconciliation: Saliva sample collected on 21SEP2020 is labelled under "Illness D3" in Viracor data and in GCL it is labelled under "Convisit D28". Please verify the correct visit for sample collected on this date.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 08:18:31
Query 'Per GCL Reconciliation: Saliva sample collected on 21SEP2020 is labelled under "Illness D3" in Viracor data and in GCL it is labelled under "Convisit D28". Please verify the correct visit for sample collected on this date.' answered with 'confirmed. correct as entered. 21sep2020 sample was collected for convisit d28' (Site from DM).	Karol Moore (b) (4) (b) (4)	10 Nov 2020 16:05:18
User opened query 'Per GCL Reconciliation: Saliva sample collected on 21SEP2020 is labelled under "Illness D3" in Viracor data and in GCL it is labelled under "Convisit D28". Please verify the correct visit for sample collected on this date.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:43:34
User entered '21 Sep 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:23:33
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 20:20:00

**US3312068**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:14:50**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:44
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:39:06

**US3312068**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:14:50**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:44
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:39:06

US3312068

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:50

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:44
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:39:06



**US3312068**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:14:50**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User entered 'SICKD1'	System	27 Aug 2020 00:39:06

US3312068

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:23:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:40:24

US3312068

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:23:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:40:24

**US3312068**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:14:50**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:23:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '12:18'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:40:24

US3312068

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User entered '25 Aug 2020 12:18'	System	27 Aug 2020 00:40:24

US3312068

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:23:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '63' in	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:40:24
DataPoint set to visible.	System	27 Aug 2020 00:39:06

US3312068

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:23:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '141' lb	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:40:24
DataPoint set to visible.	System	27 Aug 2020 00:39:06

US3312068

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:23:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:40:24



US3312068

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:23:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:40:24

**US3312068**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:14:50**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:23:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:40:24

US3312068

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:23:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '72'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:40:24

**US3312068**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:14:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User entered 'bpm'	System	27 Aug 2020 00:40:24

US3312068

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:23:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '14'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:40:24

US3312068

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User entered 'breaths/min'	System	27 Aug 2020 00:40:24

US3312068

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:23:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '102'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:40:24

US3312068

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User entered 'mmHg'	System	27 Aug 2020 00:40:24



US3312068

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:23:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '68'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:40:24

US3312068

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User entered 'mmHg'	System	27 Aug 2020 00:40:24

US3312068

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39

US3312068

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39

US3312068

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:40:34

US3312068

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:50

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:22:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:40:34

US3312068

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:14:50

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:23:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:40:42

**US3312068**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 22:14:50**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:23:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:40:42



US3312068

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:25:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4)	21 Oct 2020 20:22:31
	Karol Moore (b) (4)	
	(b) (4)	

US3312068

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:50

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:25:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '21 Sep 2020'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:22:31
	(b) (4)	

US3312068

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:50

[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 21:01:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:25:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Clinic (Clinic)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:22:31

US3312068

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
User entered 'SICKD28'	System	21 Oct 2020 20:22:31

US3312068

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:26:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:23:00
	(b) (4)	

US3312068

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:26:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '21 Sep 2020'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:23:00
	(b) (4)	

US3312068

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
User signature succeeded.	Carlos Fierro (b) (4)	24 Apr 2021 14:41:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:28:56
User closed query 'Source documents 12:08. Please update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 19:28:54
Query 'Source documents 12:08. Please update accordingly. ' answered with 'UPDATED PER SOURCE' (Site from CRA).	Karol Moore (b) (4)	22 Apr 2021 14:48:12
Signature has been broken.	(b) (4)	
User entered '12:08' reason for change: Data Entry Error	Karol Moore (b) (4)	22 Apr 2021 14:47:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 15:26:07
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:26:05
User opened query 'Source documents 12:08. Please update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 15:25:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '12:02'	(b) (4) Karol Moore (b) (4)	21 Oct 2020 20:23:00
	(b) (4)	

US3312068

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
User entered '21 Sep 2020 12:08'	System	22 Apr 2021 14:47:44
User entered '21 Sep 2020 12:02'	System	21 Oct 2020 20:23:00



US3312068

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:26:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '98.0' F	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:23:00
	(b) (4)	

US3312068

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:26:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Oral (Oral)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:23:00
	(b) (4)	

US3312068

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:26:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4)	21 Oct 2020 20:23:00
	Karol Moore (b) (4)	
	(b) (4)	

US3312068

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:26:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '63'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:23:00
	(b) (4)	

**US3312068**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:14:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
User entered 'bpm'	System	21 Oct 2020 20:23:00

US3312068

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:26:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '14'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:23:00
	(b) (4)	

US3312068

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
User entered 'breaths/min'	System	21 Oct 2020 20:23:00

US3312068

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:26:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '110'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:23:00
	(b) (4)	



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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
User entered 'mmHg'	System	21 Oct 2020 20:23:00

US3312068

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:26:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '73'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:23:00
	(b) (4)	

US3312068

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
User entered 'mmHg'	System	21 Oct 2020 20:23:00

US3312068

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57

US3312068

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:50

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57

US3312068

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:26:16
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:23:09
	(b) (4)	

US3312068

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:26:16
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '21 Sep 2020'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:23:09
	(b) (4)	

US3312068

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:14:50

[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 21:01:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:26:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:23:18
	(b) (4)	



US3312068

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:14:50

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:26:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '21 Sep 2020'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 20:23:18
	(b) (4)	

US3312068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4) (b) (4)	01 Feb 2021 20:19:12

US3312068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:50

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '27 Jan 2021'	(b) (4) Monica Atwood (b) (4)	01 Feb 2021 20:19:12

US3312068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:50

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Clinic (Clinic)'	(b) (4) Monica Atwood (b) (4)	01 Feb 2021 20:19:12

US3312068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User entered 'UNBLND_DECIDE'	System	01 Feb 2021 20:19:12

US3312068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:14:50

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '27 Jan 2021'	(b) (4) Monica Atwood (b) (4)	01 Feb 2021 20:19:33

**US3312068**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:14:50**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:31:10

**US3312068**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:14:50**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	01 Feb 2021 20:19:33



**US3312068**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:14:50**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:31:10

US3312068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:14:50

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '27 Jan 2021'	(b) (4) Monica Atwood (b) (4)	01 Feb 2021 20:19:33

US3312068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:14:50

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Placebo (Placebo)'	(b) (4) Monica Atwood (b) (4)	01 Feb 2021 20:19:33

US3312068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:14:50

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Placebo (Placebo)'	(b) (4) Monica Atwood (b) (4) (b) (4)	01 Feb 2021 20:19:33

US3312068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:14:50

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Not Administered (NA)'	(b) (4) Monica Atwood (b) (4) (b) (4)	01 Feb 2021 20:19:33

US3312068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:14:50

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4) (b) (4)	01 Feb 2021 20:19:33

US3312068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:14:50

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User entered 'I'	System	01 Feb 2021 20:19:33

US3312068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:14:50

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User entered empty.	System	01 Feb 2021 20:19:33



US3312068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	01 Feb 2021 20:19:46

US3312068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '27 Jan 2021'	(b) (4) Monica Atwood (b) (4)	01 Feb 2021 20:19:46

US3312068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '14:16'	(b) (4) Monica Atwood (b) (4)	01 Feb 2021 20:19:46

US3312068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User entered '27 Jan 2021 14:16'	System	01 Feb 2021 20:19:46

US3312068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:14:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4) (b) (4)	01 Feb 2021 20:19:58

US3312068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:14:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated "28-JAN-2021" is recorded under Participant Decision Visit / OL-D1 visit in EDC; however, in PPD portal, it is recorded as "27-JAN-2021" for OL-1 visit. Kindly review the collection date and update EDC or Preclarus portal as appropriate, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:23:00
Query 'Per GCL Lab Reconciliation: Swab: Sample dated "28-JAN-2021" is recorded under Participant Decision Visit / OL-D1 visit in EDC; however, in PPD portal, it is recorded as "27-JAN-2021" for OL-1 visit. Kindly review the collection date and update EDC or Preclarus portal as appropriate, else clarify.' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	26 Mar 2021 16:51:24
User entered '27 Jan 2021' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	26 Mar 2021 16:51:10
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated "28-JAN-2021" is recorded under Participant Decision Visit / OL-D1 visit in EDC; however, in PPD portal, it is recorded as "27-JAN-2021" for OL-1 visit. Kindly review the collection date and update EDC or Preclarus portal as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 07:39:24
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 28JAN2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:14:33
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 28JAN2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' answered with 'CONFIRMED SHIPPED. ACCESSION NUMBER: 1F633942675' (Site from DM).	Karol Moore (b) (4) (b) (4)	19 Feb 2021 18:41:44

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3312068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:14:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 28JAN2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM). User entered '28 Jan 2021'	(b) (4), (b) (6)            Monica Atwood (b) (4) (b) (4)	16 Feb 2021 07:05:53            01 Feb 2021 20:19:58

US3312068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:14:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '14:15'	(b) (4) Monica Atwood (b) (4) (b) (4)	01 Feb 2021 20:19:58



**US3312068**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:14:50**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:14:32
User entered '27 Jan 2021 14:15'	System	26 Mar 2021 16:51:10
User entered '28 Jan 2021 14:15'	System	01 Feb 2021 20:19:58

US3312068

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:14:50

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:13:00
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:27:59
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Headache, Fatigue, Joint aches in several joints ,Muscle aches all over, lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 03:25:59
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Headache, Fatigue, Joint aches in several joints ,Muscle aches all over, lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' answered with 'NA. SYMPTOMS REPORTED IN SUBJECT DIARY RESULTED IN AN ILLNESS VISIT. SEE SYMPTOMATIC COVID-19 AE' (Site from DM).	Karol Moore (b) (4) (b) (4)	19 Apr 2021 17:02:52
User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Headache, Fatigue, Joint aches in several joints ,Muscle aches all over, lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 06:53:08
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:44:32

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:14:50

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 01:10:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:14:50

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:12
User entered 'USA-US300-2020-mRNA-1273-P301000001'	System	02 Sep 2020 12:28:40
User entered 'New'	(b) (4), (b) (6)	02 Sep 2020 12:28:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:14:50

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
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)	26 Oct 2020 19:21:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 19:21:33
Data point term sent to Coder	System	26 Oct 2020 18:16:09
Coding entries removed.	(b) (4), (b) (6)	26 Oct 2020 18:15:14
User entered 'Symptomatic COVID 19' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:15:14
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 01:40:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 01:40:21
Data point term sent to Coder	System	02 Sep 2020 01:11:56
User entered 'COVID 19'	(b) (4), (b) (6)	02 Sep 2020 01:11:55

**US3312068**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:14:50**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:11:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:14:50

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:11:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:14:50

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:11:55



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:14:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User closed query 'PV Query: On 17 Aug 2020, the subject began experiencing symptoms of COVID-19 that included moderate fatigue and mild headaches. Please consider updating start date of the event to 17 Aug 2020. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:50
Query 'PV Query: On 17 Aug 2020, the subject began experiencing symptoms of COVID-19 that included moderate fatigue and mild headaches. Please consider updating start date of the event to 17 Aug 2020. ' answered with 'updated' (Site from Safety).	Karol Moore (b) (4) (b) (4)	10 Nov 2020 16:22:40
User entered '17 Aug 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	10 Nov 2020 16:22:34
User opened query 'PV Query: On 17 Aug 2020, the subject began experiencing symptoms of COVID-19 that included moderate fatigue and mild headaches. Please consider updating start date of the event to 17 Aug 2020. ' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 21:42:52
User closed query 'PV Query: Did the subject have any signs or symptoms of COVID-19 on 20 Aug 2020? Was the nasopharyngeal swab collected on 20 Aug 2020? If no, please consider updating start date to onset of signs and symptoms or date COVID-19 test was collected, whichever came first.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 16:47:35
Query 'PV Query: Did the subject have any signs or symptoms of COVID-19 on 20 Aug 2020? Was the nasopharyngeal swab collected on 20 Aug 2020? If no, please consider updating start date to onset of signs and symptoms or date COVID-19 test was collected, whichever came first.' answered with 'symptom log updated to start of symptom date of 8/17' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 18:35:27

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:14:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Did the subject have any signs or symptoms of COVID-19 on 20 Aug 2020? Was the nasopharyngeal swab collected on 20 Aug 2020? If no, please consider updating start date to onset of signs and symptoms or date COVID-19 test was collected, whichever came first.' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 19:33:14
User entered '20 Aug 2020'	(b) (4), (b) (6)	02 Sep 2020 01:11:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:14:50

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User closed query 'Start time is present for an AE thatSystem did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	02 Sep 2020 01:12:27
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Sep 2020 01:12:27
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 01:12:27
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Sep 2020 01:11:55
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	02 Sep 2020 01:11:55
User entered 'un:un' (non-conformant).	(b) (4), (b) (6)	02 Sep 2020 01:11:55

**US3312068**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:14:50**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 01:12:27
User entered '20 Aug 2020 UN:UN' (non-conformant).	System	02 Sep 2020 01:11:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:14:50

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	16 Sep 2020 19:48:43
User entered 'No (N)' reason for change: Data Entry Error	System	16 Sep 2020 19:48:43
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 19:48:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 01:11:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:14:50

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:41:43
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 19:48:51
User entered '28 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 19:48:28
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	08 Sep 2020 13:43:19
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 01:11:55

**US3312068**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:14:50**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:11:55

**US3312068**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:14:50**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 01:11:55



US3312068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:14:50

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 19:48:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	02 Sep 2020 01:11:55

**US3312068**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:14:50**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:11:55

**US3312068**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:14:50**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:11:55

**US3312068**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:14:50**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:11:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:14:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:11:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:14:50

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:11:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:14:50

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:11:55

**US3312068**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:14:50**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:11:55



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**Form: Adverse Events (1)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:11:55

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:11:55

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:11:55

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:11:55

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
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) (4), (b) (6)	25 Sep 2020 13:21:11
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	16 Sep 2020 19:48:28
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	02 Sep 2020 01:11:55

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:11:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:14:50

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 12:38:10
User closed query 'Per CDM re-query: Thank you for your answer. However, is subject withdrawn IP then please consider entering data under "Dosing discontinuation" form. Thank you!' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 10:21:25
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'updated form to "due to SARS COv2"' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 19:57:33
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	26 Oct 2020 18:38:45
Query 'Per CDM re-query: Thank you for your answer. However, is subject withdrawn IP then please consider entering data under "Dosing discontinuation" form. Thank you!' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 18:35:37
User opened query 'Per CDM re-query: Thank you for your answer. However, is subject withdrawn IP then please consider entering data under "Dosing discontinuation" form. Thank you!' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 10:54:03
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)	15 Oct 2020 10:54:03

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Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
Query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' answered with 'Subject did not withdraw-IP withdrawn per protocol due to positive result. subject remains in study' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 21:20:36
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 11:52:43
User closed query 'PV Query: Please clarify action taken with study drug due to the event of COVID-19. Please consider updating to withdrawn, if the subject will no longer be continuing in the study. ' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 12:41:52
Query 'PV Query: Please clarify action taken with study drug due to the event of COVID-19. Please consider updating to withdrawn, if the subject will no longer be continuing in the study. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 19:49:11
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 19:48:28
User opened query 'PV Query: Please clarify action taken with study drug due to the event of COVID-19. Please consider updating to withdrawn, if the subject will no longer be continuing in the study. ' (Site from Safety).	(b) (4), (b) (6)	08 Sep 2020 13:42:40
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 01:12:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 01:12:41
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 01:12:41
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 01:11:55
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 01:11:55



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Form: Adverse Events (1)

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User closed query 'Per DM CLR: Other Action Taken = None. Note that there is a CM #2 (ACETAMINOPHEN) indicated for this condition. However, it was given prior the start date of this AE. Verify if the AE and CM start/stop dates should be reconciled so the dates will align or confirm that there is no Medication given for this AE. '(Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:25:59
Query 'Per DM CLR: Other Action Taken = None. Note that there is a CM #2 (ACETAMINOPHEN) indicated for this condition. However, it was given prior the start date of this AE. Verify if the AE and CM start/stop dates should be reconciled so the dates will align or confirm that there is no Medication given for this AE. 'answered with 'updated' (Site from DM).	Karol Moore (b) (4) (b) (4)	10 Nov 2020 16:22:44
User entered '0' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	10 Nov 2020 16:22:34
User opened query 'Per DM CLR: Other Action Taken = None. Note that there is a CM #2 (ACETAMINOPHEN) indicated for this condition. However, it was given prior the start date of this AE. Verify if the AE and CM start/stop dates should be reconciled so the dates will align or confirm that there is no Medication given for this AE. '(Site from DM).	(b) (4), (b) (6)	06 Nov 2020 09:43:14
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Sep 2020 01:12:27
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 01:12:27
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Sep 2020 01:11:55

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[None](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 01:11:55

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User entered '1' reason for change: Data Entry Error	(b) (4) Karol Moore (b) (4)	10 Nov 2020 16:22:34
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:11:55

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:14:50**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:11:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:14:50

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:42:00
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 19:49:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 19:48:28
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Sep 2020 13:43:43
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 01:12:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 01:12:27
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 01:12:27
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 01:11:55
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 01:11:55

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**Form: Adverse Events (1)**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:11:55

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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:10:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:32
User closed query ' Per DM CLR: SAE Narrative indicates that IBUPROFEN was taken for the symptoms of this AE. However, there is no corresponding ConMed record that match the medication taken during the time frame of this AE. Please update applicable details accordingly. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 06:39:08
Query ' Per DM CLR: SAE Narrative indicates that IBUPROFEN was taken for the symptoms of this AE. However, there is no corresponding ConMed record that match the medication taken during the time frame of this AE. Please update applicable details accordingly. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 18:35:49
User opened query ' Per DM CLR: SAE Narrative indicates that IBUPROFEN was taken for the symptoms of this AE. However, there is no corresponding ConMed record that match the medication taken during the time frame of this AE. Please update applicable details accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 05:01:11
User closed query 'PV Query: Did the subject have any known COVID-19 exposures or contacts. ' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:21:18

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:21:14
User closed query 'PV Query: Regarding the report of "nasopharyngeal rapid polymerase chain reaction for SARS-CoV-2 was positive." Please clarify the date the nasal swab specimen was obtained and the date the test result was reported to the investigator. ' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:21:11
Query 'PV Query: Regarding the report of "nasopharyngeal rapid polymerase chain reaction for SARS-CoV-2 was positive." Please clarify the date the nasal swab specimen was obtained and the date the test result was reported to the investigator. ' answered with 'updated in narrative' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 15:21:15
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'updated in narrative' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 15:21:09
Query 'PV Query: Did the subject have any known COVID-19 exposures or contacts. ' answered with 'updated in narrative' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 15:21:00
User entered 'In response to queries: Illness visit Day 1 with NP swab done 25Aug2020, results positive-reported to site on 08Sep2020. Had exposure of COVID + individuals at school in same residence. Subject only took Ibuprofen for symptoms.' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:20:40
User opened query 'PV Query: Did the subject have any known COVID-19 exposures or contacts. ' (Site from Safety).	(b) (4), (b) (6)	08 Sep 2020 13:44:18

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EAB) (1725)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	08 Sep 2020 13:44:02
User opened query 'PV Query: Regarding the report of "nasopharyngeal rapid polymerase chain reaction for SARS-CoV-2 was positive." Please clarify the date the nasal swab specimen was obtained and the date the test result was reported to the investigator. ' (Site from Safety).	(b) (4), (b) (6)	08 Sep 2020 13:42:20
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 01:11:55

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Sep 2020 01:11:55

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 01:11:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:14:50

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:13:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User closed query 'Per DM CLR: Per Diary Dose 1 Day 9-12, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:21:27
User closed query 'Per DM CLR: Per Diary Dose 1 Day 6-7, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 16:21:20
Query 'Per DM CLR: Per Diary Dose 1 Day 9-12, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'n/a. Subject chose Grade 2 for "some interference with activity. Confirmed subject did not take over the counter medication on Days 9-12' (Site from DM).	Karol Moore (b) (4) (b) (4)	10 Nov 2020 17:02:05
Query 'Per DM CLR: Per Diary Dose 1 Day 6-7, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'See ConMed for Covid-19 symptom. This headache is Covid-19 symptom, not considered reactogenicity.' (Site from DM).	Karol Moore (b) (4) (b) (4)	10 Nov 2020 16:18:32

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:14:50

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Diary Dose 1 Day 6-7, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:37:05
User opened query 'Per DM CLR: Per Diary Dose 1 Day 9-12, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 09:58:44
User closed query 'Per CDM: According to a "Diary Dose 1", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:32:50
Query 'Per CDM: According to a "Diary Dose 1", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' answered with 'correct as entered, for AE of symptomatic covid' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 20:26:02
User opened query 'Per CDM: According to a "Diary Dose 1", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 08:00:37
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:21:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:14:50

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL; FERROUS FUMARATE; NORETHISTERONE ACETATE, PRODUCTS YNOM: LO LOESTRIN FE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Sep 2020 18:21:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Sep 2020 18:21:35
Data point term sent to Coder	System	18 Sep 2020 18:20:54
User closed query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	System	18 Sep 2020 18:20:03
Query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 18:20:03
User entered 'Lo loestrin' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 18:19:56
User opened query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	18 Aug 2020 07:23:15
Data point term sent to Coder	System	17 Aug 2020 17:22:41

US3312068

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:14:50**

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'LOLOESTROGEN'	Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:22:04

US3312068

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:14:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	17 Aug 2020 17:22:04
	(b) (4)	



US3312068

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:14:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
	(b) (4)	
User entered 'BIRTH CONTROL'	Karol Moore (b) (4)	17 Aug 2020 17:22:04
	(b) (4)	

US3312068

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:14:50**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
	(b) (4)	
User entered '1'	Karol Moore (b) (4)	17 Aug 2020 17:22:04
	(b) (4)	

US3312068

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:14:50**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
	(b) (4)	
User entered 'tablet (TABLET)'	Karol Moore (b) (4)	17 Aug 2020 17:22:04
	(b) (4)	

US3312068

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:14:50**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	17 Aug 2020 17:22:04
	(b) (4)	

US3312068

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:14:50**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
	(b) (4)	
User entered 'once daily (QD)'	Karol Moore (b) (4)	17 Aug 2020 17:22:04
	(b) (4)	

US3312068

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:14:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	17 Aug 2020 17:22:04
	(b) (4)	

US3312068

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:14:50**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	17 Aug 2020 17:22:04
	(b) (4)	

US3312068

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:14:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	17 Aug 2020 17:22:04
	(b) (4)	



US3312068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:14:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	20 Aug 2020 11:40:39
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 17:22:04
User entered 'UN Aug 2019'	Karol Moore (b) (4) (b) (4)	17 Aug 2020 17:22:04

US3312068

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:14:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	17 Aug 2020 17:22:04
	(b) (4)	

US3312068

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:14:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	17 Aug 2020 17:22:04
	(b) (4)	

US3312068

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:14:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	17 Aug 2020 17:22:04
	(b) (4)	

US3312068

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:14:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	17 Aug 2020 17:22:04
	(b) (4)	

**US3312068**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:14:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 17:22:04

US3312068

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:14:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 17:22:04

US3312068

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:14:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 17:22:04



US3312068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:56:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Oct 2020 21:14:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	29 Oct 2020 21:14:19
Data point term sent to Coder Coding entries removed.	System	26 Oct 2020 18:36:58
	(b) (4), (b) (6)	26 Oct 2020 18:36:17
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Sep 2020 09:18:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	27 Sep 2020 09:18:45
Data point term sent to Coder	System	25 Sep 2020 13:50:02
User entered 'ibuprofen'	Karol Moore (b) (4)	25 Sep 2020 13:49:35
	(b) (4)	

US3312068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:56:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'No (N)'	(b) (4)	25 Sep 2020 13:49:35
	Karol Moore (b) (4)	
	(b) (4)	

US3312068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:56:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User closed query 'Per DM CLR: Please note that the AE linked to this CM does not match this Con Med timeframe. Please review Con Med use and reconcile with AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 15:09:09
Query 'Per DM CLR: Please note that the AE linked to this CM does not match this Con Med timeframe. Please review Con Med use and reconcile with AE eCRF as appropriate.' answered with 'updated ae ecrf' (Site from DM).	Karol Moore (b) (4) (b) (4)	10 Nov 2020 16:23:02
User opened query 'Per DM CLR: Please note that the AE linked to this CM does not match this Con Med timeframe. Please review Con Med use and reconcile with AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:19:39
User entered 'Symptomatic covid-19' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:36:17
User entered 'headache/arthritis/myalgia'	Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:49:35

US3312068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:56:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '600'	Karol Moore (b) (4)	25 Sep 2020 13:49:35

US3312068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:56:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:49:35

US3312068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:56:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:49:35

US3312068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:56:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'as needed (PRN)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:49:35

US3312068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:56:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:49:35



US3312068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:56:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	25 Sep 2020 13:49:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:56:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:49:35

US3312068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:56:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '18 Aug 2020' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 20:29:19
User entered '18 Apr 2020'	Karol Moore (b) (4)	25 Sep 2020 13:49:35
	(b) (4)	

US3312068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:56:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:49:35

US3312068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:56:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:49:35

US3312068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:56:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '19 Aug 2020' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 20:29:19
User entered '19 Apr 2020'	Karol Moore (b) (4)	25 Sep 2020 13:49:35
	(b) (4)	

US3312068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:56:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 15:09:20
Query 'Per DM CLR: Was this medication taken for solicited event?' = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	Karol Moore (b) (4) (b) (4)	10 Nov 2020 16:23:26
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	10 Nov 2020 16:23:22
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:20:24
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the con med was given prior ICF. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 06:29:28
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the con med was given prior ICF. Review and update entry as appropriate.' answered with 'updated dates per source' (Site from DM).	Karol Moore (b) (4) (b) (4)	21 Oct 2020 20:29:10
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the con med was given prior ICF. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 05:45:38
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	25 Sep 2020 13:49:35

US3312068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:56:37
User entered empty.	System	25 Sep 2020 13:49:35



US3312068

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:14:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:56:37
User entered empty.	System	25 Sep 2020 13:49:35

US3312068

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:14:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:56:37
User entered empty.	System	25 Sep 2020 13:49:35

US3312068

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 22:14:50**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	18 Feb 2021 15:55:22

US3312068

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:14:50

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:45:01
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
	(b) (4)	
User closed query 'Date of dosing discontinuation is prior to Randomization Date. Please verify and reconcile.' (Site from System).	System	26 Oct 2020 18:38:58
User closed query 'Date of dosing discontinuation is prior to ICF Date. Please verify and reconcile.' (Site from System).	System	26 Oct 2020 18:38:58
User entered '28 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:38:58
User opened query 'Date of dosing discontinuation is prior to Randomization Date. Please verify and reconcile.' (Site from System).	System	26 Oct 2020 18:38:45
User opened query 'Date of dosing discontinuation is prior to ICF Date. Please verify and reconcile.' (Site from System).	System	26 Oct 2020 18:38:45
User entered '28 Apr 2020'	(b) (4), (b) (6)	26 Oct 2020 18:38:45

US3312068

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:14:50

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:45:01
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
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) (4), (b) (6)	22 Nov 2020 22:32:43
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 'SUBJECT DISING DISCONTINUATION DUE TO COVID POSITIVE AS ENTERED. EOS PAGE NOT NEEDED YET AS SUBJECT AGREES TO CONTINUE FOR SAFETY.' (Site from DM).	Monica Atwood (b) (4) (b) (4)	19 Nov 2020 21:20:52
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)	01 Nov 2020 13:07:21
User entered 'Due to SARS-COV-2 (COVID)'	(b) (4), (b) (6)	26 Oct 2020 18:38:45

US3312068

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:14:50

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:45:01
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:38:45

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'USA-US300-2020-MRNA-1273-P301000001'	System	02 Sep 2020 12:28:40

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40



**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered 'Carlos' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered 'Fierro' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40



US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered '16300 College Blvd' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:52:08
Un-reviewed for Safety.	System	27 Oct 2020 16:47:56
User entered 'Shawnee'	System	27 Oct 2020 16:47:56
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:52:08
Un-reviewed for Safety.	System	27 Oct 2020 16:47:56
User entered 'KS'	System	27 Oct 2020 16:47:56
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered 'Kansas' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered '66219' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Amendment Manager: Data point set to conformant.	(b) (4)	19 Sep 2020 07:04:46
Reviewed for Safety.	System (b) (4), (b) (6)	17 Sep 2020 12:42:13
User entered 'US' (non-conformant).	System	02 Sep 2020 12:47:38

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	11 Nov 2020 22:52:21
User entered '4'	System	27 Oct 2020 16:47:56
User entered '3'	System	22 Sep 2020 15:21:41
User entered '2'	System	17 Sep 2020 12:42:27
User entered '1'	System	02 Sep 2020 12:47:38

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'USA-US300-2020-MRNA-1273-P301000001'	System	02 Sep 2020 12:28:40

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40



**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered 'Carlos' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered 'Fierro' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40



US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered '16300 College Blvd' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:52:08
Un-reviewed for Safety.	System	27 Oct 2020 16:47:56
User entered 'Shawnee'	System	27 Oct 2020 16:47:56
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:52:08
Un-reviewed for Safety.	System	27 Oct 2020 16:47:56
User entered 'KS'	System	27 Oct 2020 16:47:56
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered 'Kansas' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered '66219' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Amendment Manager: Data point set to conformant.	(b) (4)	19 Sep 2020 07:04:46
Reviewed for Safety.	System (b) (4), (b) (6)	17 Sep 2020 12:42:13
User entered 'US' (non-conformant).	System	02 Sep 2020 12:47:38

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	11 Nov 2020 22:52:21
User entered '4'	System	27 Oct 2020 16:47:56
User entered '3'	System	22 Sep 2020 15:21:41
User entered '2'	System	17 Sep 2020 12:42:27
User entered '1'	System	02 Sep 2020 12:47:38

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (1)**

**Generated On: 11 Aug 2021 22:14:50**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '02/Sep/2020 08:47'	(b) (4) System	02 Sep 2020 12:47:38

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:14:50

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:42:13
User entered 'I'	(b) (4), (b) (6)	02 Sep 2020 12:47:38



US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'USA-US300-2020-MRNA-1273-P301000001'	System	02 Sep 2020 12:28:40

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40



US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered 'Carlos' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered 'Fierro' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered '16300 College Blvd' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:52:08
Un-reviewed for Safety.	System	27 Oct 2020 16:47:56
User entered 'Shawnee'	System	27 Oct 2020 16:47:56
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:52:08
Un-reviewed for Safety.	System	27 Oct 2020 16:47:56
User entered 'KS'	System	27 Oct 2020 16:47:56
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered 'Kansas' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered '66219' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Amendment Manager: Data point set to conformant.	(b) (4)	19 Sep 2020 07:04:46
Reviewed for Safety.	System (b) (4), (b) (6)	17 Sep 2020 12:42:13
User entered 'US' (non-conformant).	System	02 Sep 2020 12:47:38

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	11 Nov 2020 22:52:21
User entered '4'	System	27 Oct 2020 16:47:56
User entered '3'	System	22 Sep 2020 15:21:41
User entered '2'	System	17 Sep 2020 12:42:27
User entered '1'	System	02 Sep 2020 12:47:38



**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (2)**

**Generated On: 11 Aug 2021 22:14:50**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '17/Sep/2020 08:42'	(b) (4) System	17 Sep 2020 12:42:27

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:14:50

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:21:29
User entered 'I'	(b) (4), (b) (6)	17 Sep 2020 12:42:27

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'USA-US300-2020-MRNA-1273-P301000001'	System	02 Sep 2020 12:28:40

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40



**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered 'Carlos' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered 'Fierro' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered '16300 College Blvd' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:52:08
Un-reviewed for Safety.	System	27 Oct 2020 16:47:56
User entered 'Shawnee'	System	27 Oct 2020 16:47:56
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:52:08
Un-reviewed for Safety.	System	27 Oct 2020 16:47:56
User entered 'KS'	System	27 Oct 2020 16:47:56
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered 'Kansas' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered '66219' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40



US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Amendment Manager: Data point set to conformant.	(b) (4)	19 Sep 2020 07:04:46
Reviewed for Safety.	System (b) (4), (b) (6)	17 Sep 2020 12:42:13
User entered 'US' (non-conformant).	System	02 Sep 2020 12:47:38

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	11 Nov 2020 22:52:21
User entered '4'	System	27 Oct 2020 16:47:56
User entered '3'	System	22 Sep 2020 15:21:41
User entered '2'	System	17 Sep 2020 12:42:27
User entered '1'	System	02 Sep 2020 12:47:38

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (3)**

**Generated On: 11 Aug 2021 22:14:50**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '22/Sep/2020 11:21'	(b) (4) System	22 Sep 2020 15:21:41

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:14:50

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:47
User entered 'I'	(b) (4), (b) (6)	22 Sep 2020 15:21:41

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'USA-US300-2020-MRNA-1273-P301000001'	System	02 Sep 2020 12:28:40

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40



**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered 'Carlos' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered 'Fierro' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered '16300 College Blvd' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:52:08
Un-reviewed for Safety.	System	27 Oct 2020 16:47:56
User entered 'Shawnee'	System	27 Oct 2020 16:47:56
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40



US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:52:08
Un-reviewed for Safety.	System	27 Oct 2020 16:47:56
User entered 'KS'	System	27 Oct 2020 16:47:56
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered 'Kansas' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered '66219' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Amendment Manager: Data point set to conformant.	(b) (4)	19 Sep 2020 07:04:46
Reviewed for Safety.	System (b) (4), (b) (6)	17 Sep 2020 12:42:13
User entered 'US' (non-conformant).	System	02 Sep 2020 12:47:38

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	11 Nov 2020 22:52:21
User entered '4'	System	27 Oct 2020 16:47:56
User entered '3'	System	22 Sep 2020 15:21:41
User entered '2'	System	17 Sep 2020 12:42:27
User entered '1'	System	02 Sep 2020 12:47:38

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (4)**

**Generated On: 11 Aug 2021 22:14:50**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '27/Oct/2020 12:47'	(b) (4) System	27 Oct 2020 16:47:56

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:14:50

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:52:08
User entered 'I'	(b) (4), (b) (6)	27 Oct 2020 16:47:56

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'USA-US300-2020-MRNA-1273-P301000001'	System	02 Sep 2020 12:28:40

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40



**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered 'No (N)'	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered 'Carlos' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered 'Fierro' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40



US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered '16300 College Blvd' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:52:08
Un-reviewed for Safety.	System	27 Oct 2020 16:47:56
User entered 'Shawnee'	System	27 Oct 2020 16:47:56
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:52:08
Un-reviewed for Safety.	System	27 Oct 2020 16:47:56
User entered 'KS'	System	27 Oct 2020 16:47:56
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered 'Kansas' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:47
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:14:35
User entered '66219' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:14:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 12:42:13
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:51:31
Amendment Manager: User entered empty.	System	14 Sep 2020 21:51:31
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 12:47:31
User entered (b) (6)	System	02 Sep 2020 12:28:40

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:50

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
Amendment Manager: Data point set to conformant.	(b) (4)	19 Sep 2020 07:04:46
Reviewed for Safety.	System (b) (4), (b) (6)	17 Sep 2020 12:42:13
User entered 'US' (non-conformant).	System	02 Sep 2020 12:47:38

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:14:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	11 Nov 2020 22:52:21
User entered '4'	System	27 Oct 2020 16:47:56
User entered '3'	System	22 Sep 2020 15:21:41
User entered '2'	System	17 Sep 2020 12:42:27
User entered '1'	System	02 Sep 2020 12:47:38

**US3312068**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (5)**

**Generated On: 11 Aug 2021 22:14:50**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered '11/Nov/2020 17:52'	(b) (4) System	11 Nov 2020 22:52:21

US3312068

Folder: SAE USA-US300-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 22:14:50

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:30:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:34:45
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:52:21