

US3002302 (Prod: Meridian Clinical Research)

Generated By: (b) (6)

Generated On: 26 Nov 2020 08:41:20

All time stamps listed in this document are displayed in GMT

**US3002302**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 08:41:20**

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[Participant ID](#)

US3002302

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

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US3002302

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:41:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:41:20

Date of Birth (MMM yyyy)	(b) (6) 1970
Age	50
Age Units	YEARS
Age (Derived)	50
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

Generated On: 26 Nov 2020 08:41:20

Date of Informed Consent ( <i>dd MMM yyyy</i> )	15 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" 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**

**Generated On: 26 Nov 2020 08:41:20**

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

Yes ☒

No ☐

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**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 26 Nov 2020 08:41:20**

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:41:20

Condition	BILATERAL TUBAL LIGATION
Start date (dd MMM yyyy)	UN UNK 1999
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="checkbox"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1999
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1999
Start Year (derived)	1999
Stop Month and Year (derived)	JAN 1999
Stop Year (derived)	1999



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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:41:20

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:41:20

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:41:20

Condition	GENERALIZED OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:41:20

Condition	RIGHT CHRONIC ANKLE PAIN
Start date (dd MMM yyyy)	UN MAY 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

US3002302

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:41:20

Condition	RIGHT MALLEOLAR FRACTURE
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	15 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	08:41 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 08:41
Height ( <i>xxx.x</i> )	157.4 cm
Weight ( <i>xxx.x</i> )	111.4 kg
BMI ( <i>xxx.x</i> )	44.96512 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 08:41:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:41:20

Date of assessment (*dd MMM yyyy*) 15 SEP 2020

Is the participant of childbearing potential? Yes ☒ No ☐

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

If Partner medically sterile or Other, specify \_\_\_\_\_

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

Date of surgery unknown False

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

Date of last menstruation unknown False



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Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:41:20

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	15 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:20

**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

**Specify**

MERCHANDIZER

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

**No Risk Identified** False

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

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:20

<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)	True
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:41:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:41:20

What was the date of randomization? (dd MMM yyyy) 15 SEP 2020

What was the participant's randomization number? 146300

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 26 Nov 2020 08:41:20**

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:20

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)	15 SEP 2020
Time of assessment (00:00-23:59)	08:41 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 08:41
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:20

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)	15 SEP 2020
Time of assessment (00:00-23:59)	10:00 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 10:00
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:41:20

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

Generated On: 26 Nov 2020 08:41:20

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

Generated On: 26 Nov 2020 08:41:20

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) 15 SEP 2020

What was the treatment time? (00:00-23:59) 09:27 (24 HR)

Treatment Date and Time (derived) 15 SEP 2020 09:27

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:41:20

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	15 SEP 2020
Collection time ( <i>00:00-23:59</i> )	08:54 (24 HR)
Collection date and time (derived)	15 SEP 2020 08:54

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:41:20

Collection date ( <i>dd MMM yyyy</i> )			15 SEP 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:47	15 SEP 2020 08:47
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:41:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 08:41:20

**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

98.2 °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 SEP 2020 09:56

PC Open Date & Time 15 SEP 2020 09:47

PC Close Date & Time 15 SEP 2020 12:17

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 08:41:20

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °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	15 SEP 2020 19:37
PC Open Date & Time	15 SEP 2020 13:12
PC Close Date & Time	16 SEP 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 08:41:20

**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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 16 SEP 2020 12:00

PC Close Date & Time 17 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 08:41:20

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**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.

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Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.7 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

18 SEP 2020 06:46

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PC Open Date & Time

17 SEP 2020 12:00

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PC Close Date & Time

18 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 08:41:20

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 19:52

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 08:41:20

---

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

19 SEP 2020 18:07

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 08:41:20

---

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.9 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

20 SEP 2020 17:20

---

PC Open Date & Time

20 SEP 2020 12:00

---

PC Close Date & Time

21 SEP 2020 11:59

---

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 08:41:20

---

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 20:41

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 08:41:20

**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

15 SEP 2020 09:56

PC Open Date & Time

15 SEP 2020 09:47

PC Close Date & Time

15 SEP 2020 12:17

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 08:41:20

**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

15 SEP 2020 19:34

PC Open Date & Time

15 SEP 2020 13:12

PC Close Date & Time

16 SEP 2020 11:59



US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 08:41:20

**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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the  
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE  
(in mm)**

Measure the largest size across any injection site swelling/hardness  
with the ruler provided.

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 08:41:20

**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

18 SEP 2020 06:46

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 08:41:20

**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

18 SEP 2020 19:51

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 08:41:20

**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

19 SEP 2020 18:07

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 08:41:20

**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

20 SEP 2020 17:19

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 08:41:20

**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

21 SEP 2020 20:41

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3002302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 08:41:20

**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 ☐

US3002302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 08:41:20

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

No ☒

Yes ☐

PC Time stamp	15 SEP 2020 09:57
PC Open Date & Time	15 SEP 2020 09:47
PC Close Date & Time	15 SEP 2020 12:17



US3002302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 08:41:20

**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 ☐

US3002302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 08:41:20

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

No ☒

Yes ☐

PC Time stamp	15 SEP 2020 19:34
PC Open Date & Time	15 SEP 2020 13:12
PC Close Date & Time	16 SEP 2020 11:59

US3002302

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 08:41:20

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 ☐

US3002302

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 08:41:20

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

US3002302

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 08:41:20

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 ☒

US3002302

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 08:41:20

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 06:47
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3002302

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 08:41:20

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 ☒

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 08:41:20**

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 19:50
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59



US3002302

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 08:41:20

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 ☒

US3002302

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 08:41:20

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 18:07
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3002302

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 08:41:20

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 ☒

US3002302

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 08:41:20

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 17:19
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3002302

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 08:41:20

**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 ☒

US3002302

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 08:41:20

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 20:42
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3002302

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:20

Was Contact Attempted?

Yes ☒

No ☐

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

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3002302

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3002302

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:20

Was Contact Attempted?

Yes ☒

No ☐

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

02 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3002302

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002302

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:20

Was Contact Attempted?

Yes ☒

No ☐

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

09 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3002302

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002302

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:41:20

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

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:20

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 ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	
Vital Signs Date and Time (derived)	
Temperature ( <i>xxx.x</i> )	
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	
Pulse units	
Respiratory Rate ( <i>xxx</i> )	
Respiratory Rate units	
Systolic Blood Pressure ( <i>xxx</i> )	
Systolic Blood Pressure units	
Diastolic Blood Pressure ( <i>xxx</i> )	
Diastolic Blood Pressure units	

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:20

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	

US3002302

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:41:20

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.*



US3002302

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:41:20

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) \_\_\_\_\_

US3002302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:41:20

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

VISIT 2 WAS SKIPPED DUE TO CONVALESCENT PERIOD.

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? \_\_\_\_\_

US3002302

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:41:20

Was the sample collected?

Yes ☐

No ☒

Collection date (*dd MMM yyyy*)

Collection time (*00:00-23:59*)

Collection date and time (derived)

US3002302

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:41:20

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		

US3002302

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002302

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:20

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*

US3002302

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002302

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:20

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*



US3002302

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002302

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:41:20

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*

US3002302

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002302

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:41:20

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

US3002302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	05 NOV 2020
Time of assessment ( <i>00:00-23:59</i> )	08:28 (24 HR)
Vital Signs Date and Time (derived)	05 NOV 2020 08:28
Temperature ( <i>xxx.x</i> )	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	77 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3002302

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:41:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 NOV 2020

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

US3002302

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:41:20

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	05 NOV 2020
Collection time ( <i>00:00-23:59</i> )	09:14 (24 HR)
Collection date and time (derived)	05 NOV 2020 09:14

US3002302

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3002302

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 NOV 2020 00:02:02

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	12 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 NOV 2020 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	21 NOV 2020 15:31:40
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	26 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 NOV 2020 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	03 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 DEC 2020 23:59



US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	10 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 DEC 2020 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 DEC 2020 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	24 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 DEC 2020 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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31 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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04 JAN 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	07 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 JAN 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	21 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JAN 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**TIMEPOINT**

DAY 138

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59



US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	04 FEB 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 FEB 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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 <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"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

11 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

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22 FEB 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

25 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**TIMEPOINT**

DAY 173

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

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08 MAR 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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11 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAR 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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 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"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	18 MAR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 MAR 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 MAR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 MAR 2021 23:59



US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

TIMEPOINT

DAY 208

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

08 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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 <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"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**TIMEPOINT**

DAY 222

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59



US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

TIMEPOINT

DAY 229

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

29 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

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10 MAY 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**TIMEPOINT**

DAY 243

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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13 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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20 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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27 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

03 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUN 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUN 2021 23:59



US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**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 ☐

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

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28 JUN 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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="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"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	08 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 JUL 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	15 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUL 2021 23:59



US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	22 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUL 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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="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"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	12 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2021 23:59
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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	26 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	16 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 SEP 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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 ☐

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

23 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**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 ☐

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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30 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 OCT 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

TIMEPOINT

DAY 390

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

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11 OCT 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

TIMEPOINT

DAY 397

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

14 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

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25 OCT 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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="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"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

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01 NOV 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

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08 NOV 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

11 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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="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"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

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22 NOV 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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25 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 NOV 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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="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"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	02 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 DEC 2021 23:59



US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	09 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 DEC 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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="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"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

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20 DEC 2021 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	23 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	27 DEC 2021 23:59
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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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30 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 JAN 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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="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"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

06 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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13 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 JAN 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	20 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 JAN 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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27 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 JAN 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**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 ☐

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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03 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 FEB 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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="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"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

10 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**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 ☐

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 FEB 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

24 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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 ☐

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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03 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 MAR 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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="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"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

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14 MAR 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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 ☐

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	24 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 MAR 2022 23:59



US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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31 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 APR 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**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 ☐

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	07 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 APR 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	14 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 APR 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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 ☐

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	21 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 APR 2022 23:59



US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

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02 MAY 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

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09 MAY 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

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16 MAY 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

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23 MAY 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

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30 MAY 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

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06 JUN 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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°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 ☐

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

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13 JUN 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**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 ☐

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

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20 JUN 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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 ☐

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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 ☐

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	07 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 JUL 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**TIMEPOINT**

DAY 670

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

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18 JUL 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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 ☐

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

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01 AUG 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

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08 AUG 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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="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"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

11 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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25 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 AUG 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	01 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 SEP 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

08 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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="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"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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="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"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	22 SEP 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	26 SEP 2022 23:59
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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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="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"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

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

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[Patient Cloud Close Date & Time](#)

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03 OCT 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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="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"/>

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	06 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 OCT 2022 23:59



US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	13 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 OCT 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	20 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**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 ☐

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	27 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 OCT 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**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 ☐

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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03 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 NOV 2022 23:59

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US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

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 ☐

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 NOV 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 NOV 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:41:20

**TIMEPOINT**

DAY 796

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

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

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

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

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

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

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

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

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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17 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 NOV 2022 23:59

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**US3002302**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:41:20**

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*

**US3002302**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:41:20**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 08:41:20

Date of Contact	09 OCT 2020
Time of Contact	14:31
Date and Time of Contact (derived)	09 OCT 2020 14:31
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input checked="" type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 08:41:20

Symptom Day

Day 1	<input checked="" type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>



US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 08:41:20

	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 OCT 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	304 of 1981	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 08:41:20

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

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 08:41:20

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

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 08:41:20

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"/>
Day 33	<input type="checkbox"/>

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 08:41:20

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	08 OCT 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	308 of 1981	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 08:41:20

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

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Form: Symptom Log (2)

Generated On: 26 Nov 2020 08:41:20

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

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Form: Symptom Log (3)

Generated On: 26 Nov 2020 08:41:20

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"/>
Day 33	<input type="checkbox"/>



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Form: Symptom Log (3)

Generated On: 26 Nov 2020 08:41:20

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	09 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	36.9 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	312 of 1981	

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Form: Symptom Log (3)

Generated On: 26 Nov 2020 08:41:20

	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 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"/>
Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>

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Form: Symptom Log (3)

Generated On: 26 Nov 2020 08:41:20

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

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 08:41:20

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"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 08:41:20

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	316 of 1981	

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 08:41:20

	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"/>
Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 08:41:20

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

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 08:41:20

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"/>
Day 33	<input type="checkbox"/>



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Form: Symptom Log (5)

Generated On: 26 Nov 2020 08:41:20

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	320 of 1981	

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 08:41:20

	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"/>
Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 08:41:20

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

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 08:41:20

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"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 08:41:20

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	324 of 1981	

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 08:41:20

	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"/>
Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 08:41:20

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

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 08:41:20

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"/>
Day 33	<input type="checkbox"/>



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Form: Symptom Log (7)

Generated On: 26 Nov 2020 08:41:20

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	328 of 1981	

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 08:41:20

	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Muscle Aches (Myalgia)	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Body Aches	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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

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

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

Nasal Congestion	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 08:41:20

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

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 08:41:20

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"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 08:41:20

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 OCT 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	332 of 1981	

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 08:41:20

	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Muscle Aches (Myalgia)	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Body Aches	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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

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

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

Nasal Congestion	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 08:41:20

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

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 08:41:20

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"/>
Day 33	<input type="checkbox"/>



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Form: Symptom Log (9)

Generated On: 26 Nov 2020 08:41:20

	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	15 OCT 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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	336 of 1981	

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 08:41:20

	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Muscle Aches (Myalgia)	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Body Aches	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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

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

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

Nasal Congestion	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 08:41:20

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

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 08:41:20

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"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 08:41:20

	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	16 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.3 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	340 of 1981	

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 08:41:20

	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Muscle Aches (Myalgia)	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Body Aches	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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

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

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

Nasal Congestion	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 08:41:20

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

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 08:41:20

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"/>
Day 33	<input type="checkbox"/>



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Form: Symptom Log (11)

Generated On: 26 Nov 2020 08:41:20

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	344 of 1981	

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 08:41:20

	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Muscle Aches (Myalgia)	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Body Aches	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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

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

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

Nasal Congestion	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 08:41:20

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

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 08:41:20

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"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 08:41:20

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	99.0 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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	348 of 1981	

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Generated On: 26 Nov 2020 08:41:20

	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"/>

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 08:41:20

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

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Form: Symptom Log (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"/>
Day 33	<input type="checkbox"/>



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Form: Symptom Log (13)

Generated On: 26 Nov 2020 08:41:20

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.8 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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	352 of 1981	

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 08:41:20

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

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 08:41:20

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

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 08:41:20

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"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 08:41:20

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	356 of 1981	

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 08:41:20

	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Muscle Aches (Myalgia)	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Body Aches	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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

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

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

Nasal Congestion	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 08:41:20

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

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Form: Symptom Log (16)

Generated On: 26 Nov 2020 08:41:20

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"/>
Day 33	<input type="checkbox"/>



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Form: Symptom Log (16)

Generated On: 26 Nov 2020 08:41:20

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	360 of 1981	

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Form: Symptom Log (16)

Generated On: 26 Nov 2020 08:41:20

	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Muscle Aches (Myalgia)	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Body Aches	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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

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

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

Nasal Congestion	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

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Form: Symptom Log (16)

Generated On: 26 Nov 2020 08:41:20

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

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Form: Symptom Log (17)

Generated On: 26 Nov 2020 08:41:20

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"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (17)

Generated On: 26 Nov 2020 08:41:20

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	364 of 1981	

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Form: Symptom Log (17)

Generated On: 26 Nov 2020 08:41:20

	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"/>

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

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Form: Symptom Log (17)

Generated On: 26 Nov 2020 08:41:20

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

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 08:41:20

Date of Visit	09 OCT 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	09 OCT 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



US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 08:41:20

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

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

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 08:41:20

**Ventilator Support:**

High-Flow Oxygen? Yes ☐ No ☒

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Non-Invasive Ventilation? Yes ☐ No ☒

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Mechanical Ventilation? Yes ☐ No ☒

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

ECMO? Yes ☐ No ☒

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

**Evidence of Shock:**

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐ No ☒

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Evidence of Shock Requires Vasopressors Yes ☐ No ☒

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Acute Renal Dysfunction? Yes ☐ No ☒

Start Date \_\_\_\_\_

Hepatic Dysfunction? Yes ☐ No ☒

Start Date \_\_\_\_\_

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 08:41:20

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

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 26 Nov 2020 08:41:20**

---

[Generate Next COVID-19 Assessment](#)

Yes ☐  
No ☒

---

**US3002302**

**Folder: Illness Visit (1)**

**Form: Saliva Collection**

**Generated On: 26 Nov 2020 08:41:20**

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	11 OCT 2020
Day 5	Yes	13 OCT 2020
Day 7	Yes	15 OCT 2020
Day 9	Yes	17 OCT 2020
Day 14	Yes	22 OCT 2020
Day 21	No	
Day 28	No	

US3002302

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:41:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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	SICKD1

US3002302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	09 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	15:29 (24 HR)
Vital Signs Date and Time (derived)	09 OCT 2020 15:29
Height ( <i>xxx.x</i> )	157.4 cm
Weight ( <i>xxx.x</i> )	109.6 kg
Temperature ( <i>xxx.x</i> )	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	80 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3002302

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:41:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 OCT 2020

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



US3002302

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 08:41:20

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

09 OCT 2020

US3002302

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:41:20

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

US3002302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	05 NOV 2020
Time of assessment ( <i>00:00-23:59</i> )	08:28 (24 HR)
Vital Signs Date and Time (derived)	05 NOV 2020 08:28
Height ( <i>xxx.x</i> )	157.4 cm
Weight ( <i>xxx.x</i> )	45 kg
Temperature ( <i>xxx.x</i> )	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	77 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3002302

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:41:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 NOV 2020

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

US3002302

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 08:41:20

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

05 NOV 2020

US3002302

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 08:41:20

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:20

AEID	
Adverse event	TOOTH ABCESS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	20 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	27 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:20

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



US3002302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:41:20

AEID	USA-US005-2020-MRNA-1273-P30 1000005
Adverse event	COVID-19
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	07 OCT 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)	17 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
v6.020 DTW (1102)	384 of 1981

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:41:20

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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	PATIENT STATED SINUS COLD/ PRESSURE, COUGHING, SORE THROAT AND DRAINAGE. PATIENT DENIED ANY EXPOSURE TO COVID.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 08:41:20

---

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

Yes ☒

No ☐

---

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

---

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:41:20

Name of Medication	NEXIUM
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	GASTROESOPHAGEAL REFLUX DISEASE
Dose per administration	20
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:41:20

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 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"/>

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:41:20

Name of Medication	ASPIRIN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	RIGHT CHRONIC ANKLE PAIN/GENERALIZE OSTEOARTHRITIS
Dose per administration	200
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/>

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:41:20

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAY 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:41:20

Name of Medication	SUDAFED PE (PHENYLEPHRINE)
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	COVID-19
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input checked="" type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>



US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:41:20

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		08 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		08 OCT 2020
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<input type="text"/>
Interval Dosage Unit Number (derived)		<input type="text"/>
Interval Dosage Definition (derived)		802 <input type="checkbox"/>
		803 <input type="checkbox"/>
		804 <input type="checkbox"/>

US3002302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 08:41:20

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3002302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 08:41:20

Procedure/Surgery date ( <i>dd MMM yyyy</i> )	Procedure/Surgery	Indication	If indication is Other, specify
27 OCT 2020	ROOT CANAL	Adverse Event	

US3002302

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 08:41:20

Date of dosing discontinuation (dd MMM yyyy)

13 OCT 2020

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☒

Other ☐

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

US3002302

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 08:41:20

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 ☐

US3002302

Folder: SAE USA-US005-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 08:41:20

SAEID	USA-US005-2020-MRNA-1273-P301000005
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	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3002302

Folder: SAE USA-US005-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 08:41:20

SAEID	USA-US005-2020-MRNA-1273-P301000005
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	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	15/OCT/2020 12:32
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

US3002302

Folder: SAE USA-US005-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 08:41:20

SAEID	USA-US005-2020-MRNA-1273-P301000005
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	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	05/NOV/2020 23:29
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



US3002302

Folder: SAE USA-US005-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 08:41:20

SAEID	USA-US005-2020-MRNA-1273-P301000005
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	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	21/NOV/2020 10:52
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

US3002302 (Prod: Meridian Clinical Research)

**US3002302**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 08:41:20**

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3002302'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	15 Sep 2020 13:29:31

**US3002302**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:41:20**

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:58:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 16:59:49

**US3002302**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:58:51
User entered '15 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 13:29:32

**US3002302**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:58:51
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Sep 2020 16:59:49

**US3002302**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:41:20**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	15 Sep 2020 16:59:49

US3002302

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:41:20

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:51:06
User entered (b) (6) 1970'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 13:29:34



**US3002302**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:41:20**

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:51:06
User entered '50'	(b) (4), (b) (6)	15 Sep 2020 17:00:00

**US3002302**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:41:20**

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	15 Sep 2020 17:00:00

**US3002302**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:41:20**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '50'	System	15 Sep 2020 14:32:44

**US3002302**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:41:20**

[Sex](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:51:06
User entered 'Female (F)'	(b) (4), (b) (6)	15 Sep 2020 17:00:00

**US3002302**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:41:20**

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:51:06
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	15 Sep 2020 17:00:00

**US3002302**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:41:20**

[White](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:51:06
User entered '1'	(b) (4), (b) (6)	15 Sep 2020 17:00:00

**US3002302**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:41:20**

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:51:06
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:00:00

**US3002302**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:41:20**

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:51:06
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:00:00



**US3002302**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:41:20**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:51:06
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:00:00

**US3002302**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:41:20**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:51:06
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:00:00

**US3002302**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:41:20**

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:51:06
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:00:00

**US3002302**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:41:20**

[If race is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:51:06
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:00:00

**US3002302**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:41:20**

[Unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:51:06
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:00:00

**US3002302**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:41:20**

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:51:06
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:00:00

**US3002302**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 08:41:20**

**Date of Informed Consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:51:15
User entered '15 Sep 2020'	Jessica Satorie (b) (4) (b) (4)	15 Sep 2020 14:32:44

**US3002302**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	15 Sep 2020 14:32:44



**US3002302**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered '2020'	System	15 Sep 2020 14:32:44

**US3002302**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 08:41:20**

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:51:15
User entered 'Amendment 3 (3)'	Jessica Satorie (b) (4) (b) (4)	15 Sep 2020 14:32:44

**US3002302**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:51:15
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	15 Sep 2020 14:32:44

**US3002302**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:51:15
User entered empty.	Jessica Satorie (b) (4) (b) (4)	15 Sep 2020 14:32:44

**US3002302**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 08:41:20**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:51:15
User entered empty.	Jessica Satorie (b) (4) (b) (4)	15 Sep 2020 14:32:44

**US3002302**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 08:41:20**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:51:15
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	15 Sep 2020 14:32:44

**US3002302**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 08:41:20**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:51:15
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 13:29:32

**US3002302**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 08:41:20**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Sep 2020 14:32:48



**US3002302**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	15 Sep 2020 14:32:48

**US3002302**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 26 Nov 2020 08:41:20**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 17:00:42

US3002302

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:41:20

[Condition](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please note that this is not reflected in the Childbearing Potential eCRF. Please reconcile and update applicable eCRF as appropriate. Otherwise, clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 11:35:09
User opened query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please note that this is not reflected in the Childbearing Potential eCRF. Please reconcile and update applicable eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 10:58:32
User coded data point as SOC: Surgical and medical procedures, HLG: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 17:01:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 17:01:46
Data point term sent to Coder	System	15 Sep 2020 17:01:11
User entered 'Bilateral tubal ligation'	(b) (4), (b) (6)	15 Sep 2020 17:01:01

**US3002302**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered 'un UNK 1999'	(b) (4), (b) (6)	15 Sep 2020 17:01:01

**US3002302**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:01:01

**US3002302**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:01:01

**US3002302**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 08:41:20**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1999'	(b) (4), (b) (6)	15 Sep 2020 17:01:01

**US3002302**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:01:01



**US3002302**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1999'	System	15 Sep 2020 17:01:01

**US3002302**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1999'	System	15 Sep 2020 17:01:01

**US3002302**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1999'	System	15 Sep 2020 17:01:01

**US3002302**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1999'	System	15 Sep 2020 17:01:01

US3002302

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:41:20

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 17:02:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 17:02:48
Data point term sent to Coder	System	15 Sep 2020 17:02:11
User entered 'Gastroesophageal reflux disease'	(b) (4), (b) (6)	15 Sep 2020 17:01:17

**US3002302**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	(b) (4), (b) (6)	15 Sep 2020 17:01:17

**US3002302**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:01:17

**US3002302**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 17:01:17



**US3002302**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 08:41:20**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:01:17

**US3002302**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:01:17

**US3002302**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	15 Sep 2020 17:01:17

**US3002302**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2019'	System	15 Sep 2020 17:01:17

**US3002302**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 17:01:17

**US3002302**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 17:01:17

US3002302

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:41:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:02:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:02:50
Data point term sent to Coder	System	15 Sep 2020 17:02:12
User entered 'Obesity'	(b) (4), (b) (6) (b) (4)	15 Sep 2020 17:01:27

**US3002302**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Sep 2020 17:01:30
User entered 'Un UNK 2000' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 17:01:30
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Sep 2020 17:01:27
User entered 'u UNK 2000' (non-conformant).	(b) (4), (b) (6)	15 Sep 2020 17:01:27



**US3002302**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 08:41:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:01:27

**US3002302**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 08:41:20**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 17:01:27

**US3002302**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 08:41:20**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:01:27

**US3002302**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 08:41:20**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:01:27

**US3002302**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 08:41:20**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	15 Sep 2020 17:01:30
User entered empty.	System	15 Sep 2020 17:01:27

**US3002302**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 08:41:20**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2000'	System	15 Sep 2020 17:01:30
User entered empty.	System	15 Sep 2020 17:01:27

**US3002302**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 08:41:20**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 17:01:27

**US3002302**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 08:41:20**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 17:01:27



US3002302

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:41:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Generalized osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 22:54:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 22:54:44
Data point term sent to Coder	System	23 Sep 2020 22:53:51
User entered 'generalized osteoarthritis'	Jessica Satorie (b) (4)	23 Sep 2020 22:53:16

US3002302

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Jessica Satorie (b) (4) (b) (4)	23 Sep 2020 22:53:16

**US3002302**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 08:41:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Satorie (b) (4) (b) (4)	23 Sep 2020 22:53:16

**US3002302**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 08:41:20**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	23 Sep 2020 22:53:16

**US3002302**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 08:41:20**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	23 Sep 2020 22:53:16

**US3002302**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 08:41:20**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Satorie (b) (4) (b) (4)	23 Sep 2020 22:53:16

**US3002302**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 08:41:20**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	23 Sep 2020 22:53:16

**US3002302**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 08:41:20**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2015'	System	23 Sep 2020 22:53:16



**US3002302**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 08:41:20**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 22:53:16

**US3002302**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 08:41:20**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 22:53:16

US3002302

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:41:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain ankle - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 05:07:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 05:07:47
Data point term sent to Coder	System	23 Sep 2020 22:53:51
User entered 'right chronic ankle pain'	Jessica Satorie (b) (4) (b) (4)	23 Sep 2020 22:53:43

**US3002302**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered 'un May 2015'	Jessica Satorie (b) (4) (b) (4)	23 Sep 2020 22:53:43

**US3002302**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 08:41:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Satorie (b) (4) (b) (4)	23 Sep 2020 22:53:43

**US3002302**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 08:41:20**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	23 Sep 2020 22:53:43

**US3002302**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 08:41:20**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	23 Sep 2020 22:53:43

**US3002302**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 08:41:20**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Satorie (b) (4) (b) (4)	23 Sep 2020 22:53:43



**US3002302**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 08:41:20**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'May 2015'	System	23 Sep 2020 22:53:43

**US3002302**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 08:41:20**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2015'	System	23 Sep 2020 22:53:43

**US3002302**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 08:41:20**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 22:53:43

**US3002302**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 08:41:20**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 22:53:43

US3002302

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:41:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Ankle fracture, LLT: Malleolar fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 05:05:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 05:05:44
Data point term sent to Coder	System	23 Sep 2020 22:54:51
User entered 'right malleolar fracture'	Jessica Satorie (b) (4) (b) (4)	23 Sep 2020 22:54:00

**US3002302**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Jessica Satorie (b) (4) (b) (4)	23 Sep 2020 22:54:00

**US3002302**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 08:41:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Satorie (b) (4) (b) (4)	23 Sep 2020 22:54:00

**US3002302**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 08:41:20**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	23 Sep 2020 22:54:00



**US3002302**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 08:41:20**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	23 Sep 2020 22:54:00

**US3002302**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 08:41:20**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Satorie (b) (4) (b) (4)	23 Sep 2020 22:54:00

**US3002302**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 08:41:20**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	23 Sep 2020 22:54:00

**US3002302**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 08:41:20**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2015'	System	23 Sep 2020 22:54:00

**US3002302**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 08:41:20**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 22:54:00

**US3002302**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 08:41:20**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 22:54:00

**US3002302**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 17:01:56

**US3002302**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 17:01:56



**US3002302**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered '08:41'	(b) (4), (b) (6)	15 Sep 2020 17:01:56

**US3002302**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered '15 Sep 2020 08:41'	System	15 Sep 2020 17:01:56

US3002302

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered '157.4' cm	(b) (4), (b) (6)	15 Sep 2020 17:01:56
DataPoint set to visible.	System	15 Sep 2020 14:32:48

US3002302

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:20

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '111.4' kg	(b) (4), (b) (6)	15 Sep 2020 17:01:56
DataPoint set to visible.	System	15 Sep 2020 14:32:48

**US3002302**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

**BMI (xxx.x)**

Audit	User	Time (GMT)
User entered '44.96512'	System	15 Sep 2020 17:01:56
DataPoint set to visible.	System	15 Sep 2020 14:32:48

**US3002302**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	15 Sep 2020 17:01:56
DataPoint set to visible.	System	15 Sep 2020 14:32:48

**US3002302**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
Query 'Please enter Temp.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 18:58:42
User opened query 'Please enter Temp.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 18:50:07
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Sep 2020 17:01:56

**US3002302**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:01:56



**US3002302**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:01:56

**US3002302**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Sep 2020 17:01:56

**US3002302**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Sep 2020 17:01:56

US3002302

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Sep 2020 17:01:56

**US3002302**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Sep 2020 17:01:56

US3002302

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Sep 2020 17:01:56

**US3002302**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Sep 2020 17:01:56

US3002302

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Sep 2020 17:01:56



**US3002302**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Sep 2020 17:01:56

**US3002302**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 08:41:20**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 17:02:02

**US3002302**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 08:41:20**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 17:02:02

**US3002302**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 08:41:20**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 17:02:10

US3002302

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:41:20

Is the participant of childbearing potential?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 17:02:10

**US3002302**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 08:41:20**

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:02:10

US3002302

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:41:20

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:02:10

US3002302

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:02:10



**US3002302**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 08:41:20**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:02:10

US3002302

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:02:10

**US3002302**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 08:41:20**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:02:10

US3002302

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:41:20

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 17:02:18

**US3002302**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 08:41:20**

**Date of test** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 17:02:18

**US3002302**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 08:41:20**

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	(b) (4), (b) (6)	15 Sep 2020 17:02:18

**US3002302**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 08:41:20**

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	15 Sep 2020 17:02:18

US3002302

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:41:20

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please consider entering "No" for this field as screening and VID1 have occurred on the same day.	(b) (4), (b) (6)	12 Oct 2020 07:22:19
' (Site from DM). Query 'Per CDM: Please consider entering "No" for this field as screening and VID1 have occurred on the same day.	(b) (4), (b) (6)	09 Oct 2020 20:33:51
' answered with 'updated' (Site from DM). User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 20:33:47
User opened query 'Per CDM: Please consider entering "No" for this field as screening and VID1 have occurred on the same day.	(b) (4), (b) (6)	08 Oct 2020 08:16:28
' (Site from DM). User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:02:18



**US3002302**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 08:41:20**

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:02:18

**US3002302**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 08:41:20**

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:02:18

**US3002302**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 17:02:18

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:00:24



US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

**US3002302**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

**US3002302**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

**US3002302**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 08:41:20**

**Other**

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:20

[Specify](#)

Audit	User	Time (GMT)
User entered 'Merchandizer'	(b) (4), (b) (6)	15 Sep 2020 17:00:24



US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:20

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

**US3002302**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

**US3002302**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 08:41:20**

**Other**

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:41:20

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:00:24



**US3002302**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:41:20**

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:58:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 17:02:26

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:58:39
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 17:02:26

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:58:39
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Sep 2020 17:02:26

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:41:20**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	15 Sep 2020 17:02:26

US3002302

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered '15 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	15 Sep 2020 14:09:18

US3002302

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:41:20

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '146300'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	15 Sep 2020 14:09:18

US3002302

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	15 Sep 2020 14:09:18

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:02:38



**US3002302**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:02:38

US3002302

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 17:02:38

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:02:38

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 08:41:20**

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:02:38

US3002302

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 08:46:11
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 17:26:10
User entered 'No (N)'	(b) (4), (b) (6)	02 Nov 2020 17:26:07
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 19:01:00
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:14:16
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:14:14

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:41:20

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:41:20

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Sep 2020 17:03:21

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 26 Nov 2020 08:41:20**

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Sep 2020 17:03:21



US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:41:20

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Sep 2020 17:03:21

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	15 Sep 2020 17:03:21

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 17:03:21

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:41:20**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 17:03:21

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered '08:41'	(b) (4), (b) (6)	15 Sep 2020 17:03:21

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered '15 Sep 2020 08:41'	System	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	(b) (4), (b) (6)	15 Sep 2020 17:03:21

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	15 Sep 2020 17:03:21



US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:20

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '77'	(b) (4), (b) (6)	15 Sep 2020 17:03:21

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered '14'	(b) (4), (b) (6)	15 Sep 2020 17:03:21

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Sep 2020 17:03:21

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered '133'	(b) (4), (b) (6)	15 Sep 2020 17:03:21

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '89'	(b) (4), (b) (6)	15 Sep 2020 17:03:21



**US3002302**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:41:20

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:41:20

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Sep 2020 17:03:21

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	15 Sep 2020 17:03:21

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 17:03:21

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:41:20**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 17:03:21

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered '10:00'	(b) (4), (b) (6)	15 Sep 2020 17:03:21

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered '15 Sep 2020 10:00'	System	15 Sep 2020 17:03:21



US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	(b) (4), (b) (6)	15 Sep 2020 17:03:21

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	15 Sep 2020 17:03:21

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:41:20**

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '86'	(b) (4), (b) (6)	15 Sep 2020 17:03:21

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	15 Sep 2020 17:03:21

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '128'	(b) (4), (b) (6)	15 Sep 2020 17:03:21



**US3002302**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '80'	(b) (4), (b) (6)	15 Sep 2020 17:03:21

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:41:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:03:26

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 08:41:20**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:03:26

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 08:41:20**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:03:31

US3002302

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:41:20

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:03:31

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 08:41:20**

[Test performed](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:03:31



**US3002302**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 08:41:20**

[Result](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:03:31

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 08:41:20**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 17:03:34
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:03:31

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 08:41:20**

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:03:31

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 08:41:20**

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:03:31

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 17:03:31

US3002302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:41:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	15 Sep 2020 14:33:12

US3002302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:41:20

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	15 Sep 2020 14:33:12

US3002302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	15 Sep 2020 14:33:12



**US3002302**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 08:41:20**

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	15 Sep 2020 14:33:12

US3002302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:41:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Jessica Satorie (b) (4) (b) (4)	15 Sep 2020 14:33:12

US3002302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered '09:27'	Jessica Satorie (b) (4) (b) (4)	15 Sep 2020 14:33:12

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 08:41:20**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 09:27'	System	15 Sep 2020 14:33:12

US3002302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:41:20

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Jessica Satorie (b) (4) (b) (4)	15 Sep 2020 14:33:12

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 08:41:20**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 08:41:20**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	15 Sep 2020 14:33:12

US3002302

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:41:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 17:03:49



**US3002302**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 08:41:20**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 17:03:49

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 08:41:20**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '08:54'	(b) (4), (b) (6)	15 Sep 2020 17:03:49

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered '15 Sep 2020 08:54'	System	15 Sep 2020 17:03:49

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 26 Nov 2020 08:41:20**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 17:04:00

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	15 Sep 2020 17:04:00

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 17:04:00

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 08:41:20**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
User entered '08:47'	(b) (4), (b) (6)	15 Sep 2020 17:04:00

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered '15 Sep 2020 08:47'	System	15 Sep 2020 17:04:00



**US3002302**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	15 Sep 2020 17:04:00

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:04:00

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 08:41:20**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:04:00

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 17:04:00

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:41:20**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 17:04:19

**US3002302**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:41:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 17:04:19

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 14:33:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 08:41:20**

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T09:55:57', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '93e4f6c8-37b2-413a-b43c-6d04ddec2639'	System	15 Sep 2020 14:56:22
User entered 'Yes (Y)'	System	15 Sep 2020 14:56:22



**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 08:41:20**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T09:56:03', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '93e4f6c8-37b2-413a-b43c-6d04ddec2639'	System	15 Sep 2020 14:56:22
User entered '98.2'	System	15 Sep 2020 14:56:22

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T09:56:09', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '93e4f6c8-37b2-413a-b43c-6d04ddec2639'	System	15 Sep 2020 14:56:22
User entered 'No (N)'	System	15 Sep 2020 14:56:22

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T09:56:16', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '93e4f6c8-37b2-413a-b43c-6d04ddec2639'	System	15 Sep 2020 14:56:22
User entered '15 Sep 2020 09:56'	System	15 Sep 2020 14:56:22

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 09:47'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:17'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 14:33:12
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 08:41:20**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T19:37:15', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '20d523f6-5dd6-4765-a25a-355a03ffc6ae'	System	16 Sep 2020 00:37:34
User entered 'Yes (Y)'	System	16 Sep 2020 00:37:34

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 08:41:20**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T19:37:21', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '20d523f6-5dd6-4765-a25a-355a03ffc6ae' User entered '97.5'	System	16 Sep 2020 00:37:34
	System	16 Sep 2020 00:37:34



**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T19:37:27', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '20d523f6-5dd6-4765-a25a-355a03ffc6ae'	System	16 Sep 2020 00:37:34
User entered 'No (N)'	System	16 Sep 2020 00:37:34

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T19:37:30', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '20d523f6-5dd6-4765-a25a-355a03ffc6ae'	System	16 Sep 2020 00:37:34
User entered '15 Sep 2020 19:37'	System	16 Sep 2020 00:37:34

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 13:12'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 14:33:12
User entered 'Day 2'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 14:33:12
User entered 'Day 3'	System	15 Sep 2020 14:33:12



**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 08:41:20**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T06:46:11', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'bd427e40-b40b-4f83-943c-126839271fef'	System	18 Sep 2020 11:46:36
User entered 'Yes (Y)'	System	18 Sep 2020 11:46:36

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 08:41:20**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T06:46:23', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'bd427e40-b40b-4f83-943c-126839271fef'	System	18 Sep 2020 11:46:36
User entered '97.7'	System	18 Sep 2020 11:46:36

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T06:46:27', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'bd427e40-b40b-4f83-943c-126839271fef'	System	18 Sep 2020 11:46:36
User entered 'No (N)'	System	18 Sep 2020 11:46:36

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T06:46:31', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'bd427e40-b40b-4f83-943c-126839271fef'	System	18 Sep 2020 11:46:36
User entered '18 Sep 2020 06:46'	System	18 Sep 2020 11:46:36

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 14:33:12
User entered 'Day 4'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 08:41:20**

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T19:52:27', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '5986b75e-4e61-484a-aeb8-6590e27581f2'	System	19 Sep 2020 00:52:51
User entered 'Yes (Y)'	System	19 Sep 2020 00:52:51



**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 08:41:20**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T19:52:34', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '5986b75e-4e61-484a-aeb8-6590e27581f2'	System	19 Sep 2020 00:52:51
User entered '97.0'	System	19 Sep 2020 00:52:51

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T19:52:45', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '5986b75e-4e61-484a-aeb8-6590e27581f2'	System	19 Sep 2020 00:52:51
User entered 'No (N)'	System	19 Sep 2020 00:52:51

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T19:52:48', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '5986b75e-4e61-484a-aeb8-6590e27581f2'	System	19 Sep 2020 00:52:51
User entered '18 Sep 2020 19:52'	System	19 Sep 2020 00:52:51

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 14:33:12
User entered 'Day 5'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 08:41:20**

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-19T18:07:37', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '63022ca7-5615-436f-82e6-b980c4e31307'	System	19 Sep 2020 23:07:59
User entered 'Yes (Y)'	System	19 Sep 2020 23:07:59

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 08:41:20**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-19T18:07:46', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '63022ca7-5615-436f-82e6-b980c4e31307'	System	19 Sep 2020 23:07:59
User entered '97.5'	System	19 Sep 2020 23:07:59



**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-19T18:07:51', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '63022ca7-5615-436f-82e6-b980c4e31307'	System	19 Sep 2020 23:07:59
User entered 'No (N)'	System	19 Sep 2020 23:07:59

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-19T18:07:54', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '63022ca7-5615-436f-82e6-b980c4e31307'	System	19 Sep 2020 23:07:59
User entered '19 Sep 2020 18:07'	System	19 Sep 2020 23:07:59

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 14:33:12
User entered 'Day 6'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 08:41:20**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-20T17:20:01', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'deb7d658-49ae-493a-ab50-b2bc27363953'	System	20 Sep 2020 22:20:15
User entered 'Yes (Y)'	System	20 Sep 2020 22:20:15

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 08:41:20**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-20T17:20:07', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'deb7d658-49ae-493a-ab50-b2bc27363953'	System	20 Sep 2020 22:20:15
User entered '97.9'	System	20 Sep 2020 22:20:15

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-20T17:20:11', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'deb7d658-49ae-493a-ab50-b2bc27363953'	System	20 Sep 2020 22:20:15
User entered 'No (N)'	System	20 Sep 2020 22:20:15



**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-20T17:20:14', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'deb7d658-49ae-493a-ab50-b2bc27363953'	System	20 Sep 2020 22:20:15
User entered '20 Sep 2020 17:20'	System	20 Sep 2020 22:20:15

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 14:33:12
User entered 'Day 7'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 08:41:20**

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-21T20:41:15', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'fb274a86-2a59-4af9-8cf8-95e91101c516'	System	22 Sep 2020 01:41:30
User entered 'Yes (Y)'	System	22 Sep 2020 01:41:30

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 08:41:20**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-21T20:41:20', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'fb274a86-2a59-4af9-8cf8-95e91101c516'	System	22 Sep 2020 01:41:30
User entered '97.9'	System	22 Sep 2020 01:41:30

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-21T20:41:24', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'fb274a86-2a59-4af9-8cf8-95e91101c516'	System	22 Sep 2020 01:41:30
User entered 'No (N)'	System	22 Sep 2020 01:41:30

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-21T20:41:27', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'fb274a86-2a59-4af9-8cf8-95e91101c516'	System	22 Sep 2020 01:41:30
User entered '21 Sep 2020 20:41'	System	22 Sep 2020 01:41:30



**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 14:33:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 08:41:20**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T09:56:31', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'd012e46b-2885-495d-8170-73235a266bb7'	System	15 Sep 2020 14:56:56
User entered 'None (1)'	System	15 Sep 2020 14:56:56

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T09:56:34', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'd012e46b-2885-495d-8170-73235a266bb7'	System	15 Sep 2020 14:56:56
User entered 'No (N)'	System	15 Sep 2020 14:56:56

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T09:56:36', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'd012e46b-2885-495d-8170-73235a266bb7'	System	15 Sep 2020 14:56:56
User entered 'No (N)'	System	15 Sep 2020 14:56:56

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 08:41:20**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T09:56:42', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'd012e46b-2885-495d-8170-73235a266bb7'	System	15 Sep 2020 14:56:56
User entered 'None (1)'	System	15 Sep 2020 14:56:56

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T09:56:55', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'd012e46b-2885-495d-8170-73235a266bb7'	System	15 Sep 2020 14:56:56
User entered '15 Sep 2020 09:56'	System	15 Sep 2020 14:56:56



**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 09:47'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:17'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 14:33:12
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 08:41:20**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T19:34:16', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '738f826a-ba6b-4812-a4d0-01471da6effe'	System	16 Sep 2020 00:34:34
User entered 'None (1)'	System	16 Sep 2020 00:34:34

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T19:34:21', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '738f826a-ba6b-4812-a4d0-01471da6effe'	System	16 Sep 2020 00:34:34
User entered 'No (N)'	System	16 Sep 2020 00:34:34

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T19:34:25', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '738f826a-ba6b-4812-a4d0-01471da6effe'	System	16 Sep 2020 00:34:34
User entered 'No (N)'	System	16 Sep 2020 00:34:34

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 08:41:20**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T19:34:28', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '738f826a-ba6b-4812-a4d0-01471da6effe'	System	16 Sep 2020 00:34:34
User entered 'None (1)'	System	16 Sep 2020 00:34:34

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T19:34:31', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '738f826a-ba6b-4812-a4d0-01471da6effe' User entered '15 Sep 2020 19:34'	System	16 Sep 2020 00:34:34
	System	16 Sep 2020 00:34:34



**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 13:12'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 14:33:12
User entered 'Day 2'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 14:33:12
User entered 'Day 3'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 08:41:20**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T06:46:38', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'a468e37a-e58f-4c2f-86a4-989f40fd4885'	System	18 Sep 2020 11:46:53
User entered 'None (1)'	System	18 Sep 2020 11:46:53

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T06:46:42', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'a468e37a-e58f-4c2f-86a4-989f40fd4885'	System	18 Sep 2020 11:46:53
User entered 'No (N)'	System	18 Sep 2020 11:46:53



**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T06:46:45', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'a468e37a-e58f-4c2f-86a4-989f40fd4885'	System	18 Sep 2020 11:46:53
User entered 'No (N)'	System	18 Sep 2020 11:46:53

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 08:41:20**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T06:46:48', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'a468e37a-e58f-4c2f-86a4-989f40fd4885'	System	18 Sep 2020 11:46:53
User entered 'None (1)'	System	18 Sep 2020 11:46:53

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T06:46:50', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'a468e37a-e58f-4c2f-86a4-989f40fd4885'	System	18 Sep 2020 11:46:53
User entered '18 Sep 2020 06:46'	System	18 Sep 2020 11:46:53

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 14:33:12
User entered 'Day 4'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 08:41:20**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T19:51:14', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '8489b873-6450-43c0-9e9f-7163fdb029c'	System	19 Sep 2020 00:51:27
User entered 'None (1)'	System	19 Sep 2020 00:51:27

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T19:51:12', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '8489b873-6450-43c0-9e9f-7163fdb029c'	System	19 Sep 2020 00:51:27
User entered 'No (N)'	System	19 Sep 2020 00:51:27



**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T19:51:12', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '8489b873-6450-43c0-9e9f-7163fdb029c'	System	19 Sep 2020 00:51:27
User entered 'No (N)'	System	19 Sep 2020 00:51:27

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 08:41:20**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T19:51:19', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '8489b873-6450-43c0-9e9f-7163fdb029c'	System	19 Sep 2020 00:51:27
User entered 'None (1)'	System	19 Sep 2020 00:51:27

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T19:51:24', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '8489b873-6450-43c0-9e9f-7163fdb029c'	System	19 Sep 2020 00:51:27
User entered '18 Sep 2020 19:51'	System	19 Sep 2020 00:51:27

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 14:33:12
User entered 'Day 5'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 08:41:20**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-19T18:07:18', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'b184fbb0-3168-4d00-8c12-b06f29622016'	System	19 Sep 2020 23:07:32
User entered 'None (1)'	System	19 Sep 2020 23:07:32

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-19T18:07:22', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'b184fbb0-3168-4d00-8c12-b06f29622016'	System	19 Sep 2020 23:07:32
User entered 'No (N)'	System	19 Sep 2020 23:07:32



**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-19T18:07:25', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'b184fbb0-3168-4d00-8c12-b06f29622016'	System	19 Sep 2020 23:07:32
User entered 'No (N)'	System	19 Sep 2020 23:07:32

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 08:41:20**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-19T18:07:28', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'b184fbb0-3168-4d00-8c12-b06f29622016'	System	19 Sep 2020 23:07:32
User entered 'None (1)'	System	19 Sep 2020 23:07:32

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-19T18:07:30', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'b184fbb0-3168-4d00-8c12-b06f29622016'	System	19 Sep 2020 23:07:32
User entered '19 Sep 2020 18:07'	System	19 Sep 2020 23:07:32

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 14:33:12
User entered 'Day 6'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 08:41:20**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-20T17:19:33', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '47150069-2d2b-4074-a3da-8282379bc85f'	System	20 Sep 2020 22:19:58
User entered 'None (1)'	System	20 Sep 2020 22:19:58

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-20T17:19:46', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '47150069-2d2b-4074-a3da-8282379bc85f'	System	20 Sep 2020 22:19:58
User entered 'No (N)'	System	20 Sep 2020 22:19:58



**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-20T17:19:49', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '47150069-2d2b-4074-a3da-8282379bc85f'	System	20 Sep 2020 22:19:58
User entered 'No (N)'	System	20 Sep 2020 22:19:58

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 08:41:20**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-20T17:19:53', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '47150069-2d2b-4074-a3da-8282379bc85f' User entered 'None (1)'	System	20 Sep 2020 22:19:58
	System	20 Sep 2020 22:19:58

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-20T17:19:55', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '47150069-2d2b-4074-a3da-8282379bc85f'	System	20 Sep 2020 22:19:58
User entered '20 Sep 2020 17:19'	System	20 Sep 2020 22:19:58

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 14:33:12
User entered 'Day 7'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 08:41:20**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-21T20:41:38', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'f78579bc-4624-45b7-9993-d372348c2212'	System	22 Sep 2020 01:41:58
User entered 'None (1)'	System	22 Sep 2020 01:41:58

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-21T20:41:43', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'f78579bc-4624-45b7-9993-d372348c2212'	System	22 Sep 2020 01:41:58
User entered 'No (N)'	System	22 Sep 2020 01:41:58



**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-21T20:41:48', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'f78579bc-4624-45b7-9993-d372348c2212'	System	22 Sep 2020 01:41:58
User entered 'No (N)'	System	22 Sep 2020 01:41:58

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 08:41:20**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-21T20:41:51', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'f78579bc-4624-45b7-9993-d372348c2212'	System	22 Sep 2020 01:41:58
User entered 'None (1)'	System	22 Sep 2020 01:41:58

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-21T20:41:57', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'f78579bc-4624-45b7-9993-d372348c2212'	System	22 Sep 2020 01:41:58
User entered '21 Sep 2020 20:41'	System	22 Sep 2020 01:41:58

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 14:33:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:41:20**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T09:57:01', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '89f8d823-a4c5-494c-abd3-1ccdf052d3f3'	System	15 Sep 2020 14:57:28
User entered 'None (0)'	System	15 Sep 2020 14:57:28

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:41:20**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T09:57:03', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '89f8d823-a4c5-494c-abd3-1ccdf052d3f3'	System	15 Sep 2020 14:57:28
User entered 'None (0)'	System	15 Sep 2020 14:57:28



**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:41:20**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T09:57:07', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '89f8d823-a4c5-494c-abd3-1ccdf052d3f3'	System	15 Sep 2020 14:57:28
User entered 'None (0)'	System	15 Sep 2020 14:57:28

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:41:20**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T09:57:11', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '89f8d823-a4c5-494c-abd3-1ccdf052d3f3'	System	15 Sep 2020 14:57:28
User entered 'None (0)'	System	15 Sep 2020 14:57:28

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:41:20**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T09:57:13', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '89f8d823-a4c5-494c-abd3-1ccdf052d3f3'	System	15 Sep 2020 14:57:28
User entered 'None (0)'	System	15 Sep 2020 14:57:28

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:41:20**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T09:57:17', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '89f8d823-a4c5-494c-abd3-1ccdf052d3f3'	System	15 Sep 2020 14:57:28
User entered 'None (0)'	System	15 Sep 2020 14:57:28

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T09:57:23', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '89f8d823-a4c5-494c-abd3-1ccdf052d3f3'	System	15 Sep 2020 14:57:28
User entered 'No (N)'	System	15 Sep 2020 14:57:28

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T09:57:26', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '89f8d823-a4c5-494c-abd3-1ccdf052d3f3'	System	15 Sep 2020 14:57:28
User entered '15 Sep 2020 09:57'	System	15 Sep 2020 14:57:28

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 09:47'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:17'	System	15 Sep 2020 14:33:12



**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 14:33:12
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:41:20**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T19:33:40', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'abd67a0b-d6b3-44be-9de3-8a8da69b6efa' User entered 'None (0)'	System	16 Sep 2020 00:34:12
	System	16 Sep 2020 00:34:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:41:20**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T19:33:42', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'abd67a0b-d6b3-44be-9de3-8a8da69b6efa' User entered 'None (0)'	System	16 Sep 2020 00:34:12
	System	16 Sep 2020 00:34:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:41:20**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T19:33:46', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'abd67a0b-d6b3-44be-9de3-8a8da69b6efa' User entered 'None (0)'	System	16 Sep 2020 00:34:12
	System	16 Sep 2020 00:34:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:41:20**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T19:33:48', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'abd67a0b-d6b3-44be-9de3-8a8da69b6efa' User entered 'None (0)'	System	16 Sep 2020 00:34:12
	System	16 Sep 2020 00:34:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:41:20**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T19:33:51', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'abd67a0b-d6b3-44be-9de3-8a8da69b6efa' User entered 'None (0)'	System	16 Sep 2020 00:34:12
	System	16 Sep 2020 00:34:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:41:20**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T19:33:54', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'abd67a0b-d6b3-44be-9de3-8a8da69b6efa' User entered 'None (0)'	System	16 Sep 2020 00:34:12
	System	16 Sep 2020 00:34:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T19:33:59', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'abd67a0b-d6b3-44be-9de3-8a8da69b6efa'	System	16 Sep 2020 00:34:12
User entered 'No (N)'	System	16 Sep 2020 00:34:12



**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-15T19:34:08', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'abd67a0b-d6b3-44be-9de3-8a8da69b6efa' User entered '15 Sep 2020 19:34'	System	16 Sep 2020 00:34:12
	System	16 Sep 2020 00:34:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 13:12'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 14:33:12
User entered 'Day 2'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 14:33:12
User entered 'Day 3'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 08:41:20**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T06:47:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '11c5f1e9-58dd-47a6-93c3-6f4bc76f0881'	System	18 Sep 2020 11:47:27
User entered 'None (0)'	System	18 Sep 2020 11:47:27



**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 08:41:20**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T06:47:03', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '11c5f1e9-58dd-47a6-93c3-6f4bc76f0881'	System	18 Sep 2020 11:47:27
User entered 'None (0)'	System	18 Sep 2020 11:47:27

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 08:41:20**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T06:47:08', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '11c5f1e9-58dd-47a6-93c3-6f4bc76f0881'	System	18 Sep 2020 11:47:27
User entered 'None (0)'	System	18 Sep 2020 11:47:27

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 08:41:20**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T06:47:11', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '11c5f1e9-58dd-47a6-93c3-6f4bc76f0881'	System	18 Sep 2020 11:47:27
User entered 'None (0)'	System	18 Sep 2020 11:47:27

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 08:41:20**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T06:47:14', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '11c5f1e9-58dd-47a6-93c3-6f4bc76f0881'	System	18 Sep 2020 11:47:27
User entered 'None (0)'	System	18 Sep 2020 11:47:27

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 08:41:20**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T06:47:17', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '11c5f1e9-58dd-47a6-93c3-6f4bc76f0881'	System	18 Sep 2020 11:47:27
User entered 'None (0)'	System	18 Sep 2020 11:47:27

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T06:47:22', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '11c5f1e9-58dd-47a6-93c3-6f4bc76f0881'	System	18 Sep 2020 11:47:27
User entered 'No (N)'	System	18 Sep 2020 11:47:27

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T06:47:25', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '11c5f1e9-58dd-47a6-93c3-6f4bc76f0881' User entered '18 Sep 2020 06:47'	System	18 Sep 2020 11:47:27
	System	18 Sep 2020 11:47:27

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 14:33:12



**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 14:33:12
User entered 'Day 4'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 08:41:20**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T19:50:39', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '0747160e-8895-49cf-af83-ad62f4b90f57'	System	19 Sep 2020 00:51:00
User entered 'None (0)'	System	19 Sep 2020 00:51:00

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 08:41:20**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T19:50:42', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '0747160e-8895-49cf-af83-ad62f4b90f57'	System	19 Sep 2020 00:51:00
User entered 'None (0)'	System	19 Sep 2020 00:51:00

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 08:41:20**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T19:50:44', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '0747160e-8895-49cf-af83-ad62f4b90f57'	System	19 Sep 2020 00:51:00
User entered 'None (0)'	System	19 Sep 2020 00:51:00

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 08:41:20**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T19:50:47', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '0747160e-8895-49cf-af83-ad62f4b90f57'	System	19 Sep 2020 00:51:00
User entered 'None (0)'	System	19 Sep 2020 00:51:00

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 08:41:20**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T19:50:49', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '0747160e-8895-49cf-af83-ad62f4b90f57'	System	19 Sep 2020 00:51:00
User entered 'None (0)'	System	19 Sep 2020 00:51:00

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 08:41:20**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T19:50:51', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '0747160e-8895-49cf-af83-ad62f4b90f57'	System	19 Sep 2020 00:51:00
User entered 'None (0)'	System	19 Sep 2020 00:51:00



**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T19:50:55', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '0747160e-8895-49cf-af83-ad62f4b90f57'	System	19 Sep 2020 00:51:00
User entered 'No (N)'	System	19 Sep 2020 00:51:00

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-18T19:50:58', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '0747160e-8895-49cf-af83-ad62f4b90f57'	System	19 Sep 2020 00:51:00
User entered '18 Sep 2020 19:50'	System	19 Sep 2020 00:51:00

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 14:33:12
User entered 'Day 5'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 08:41:20**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-19T18:06:43', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '394eb249-373e-4f2a-a7e7-a8d4537ffceb'	System	19 Sep 2020 23:07:17
User entered 'None (0)'	System	19 Sep 2020 23:07:17

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 08:41:20**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-19T18:06:46', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '394eb249-373e-4f2a-a7e7-a8d4537ffceb'	System	19 Sep 2020 23:07:17
User entered 'None (0)'	System	19 Sep 2020 23:07:17

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 08:41:20**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-19T18:06:49', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '394eb249-373e-4f2a-a7e7-a8d4537ffceb'	System	19 Sep 2020 23:07:17
User entered 'None (0)'	System	19 Sep 2020 23:07:17



**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 08:41:20**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-19T18:06:52', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '394eb249-373e-4f2a-a7e7-a8d4537ffceb'	System	19 Sep 2020 23:07:17
User entered 'None (0)'	System	19 Sep 2020 23:07:17

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 08:41:20**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-19T18:06:54', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '394eb249-373e-4f2a-a7e7-a8d4537ffceb'	System	19 Sep 2020 23:07:17
User entered 'None (0)'	System	19 Sep 2020 23:07:17

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 08:41:20**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-19T18:06:58', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '394eb249-373e-4f2a-a7e7-a8d4537ffceb'	System	19 Sep 2020 23:07:17
User entered 'None (0)'	System	19 Sep 2020 23:07:17

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-19T18:07:10', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '394eb249-373e-4f2a-a7e7-a8d4537ffceb' User entered 'No (N)'	System	19 Sep 2020 23:07:17

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-19T18:07:13', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '394eb249-373e-4f2a-a7e7-a8d4537ffceb' User entered '19 Sep 2020 18:07'	System	19 Sep 2020 23:07:17
	System	19 Sep 2020 23:07:17

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 14:33:12
User entered 'Day 6'	System	15 Sep 2020 14:33:12



**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 08:41:20**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-20T17:19:13', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'faa3493a-322c-48bc-a8ec-838d3bb2d71f'	System	20 Sep 2020 22:19:31
User entered 'None (0)'	System	20 Sep 2020 22:19:31

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 08:41:20**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-20T17:19:16', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'faa3493a-322c-48bc-a8ec-838d3bb2d71f'	System	20 Sep 2020 22:19:31
User entered 'None (0)'	System	20 Sep 2020 22:19:31

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 08:41:20**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-20T17:19:18', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'faa3493a-322c-48bc-a8ec-838d3bb2d71f'	System	20 Sep 2020 22:19:31
User entered 'None (0)'	System	20 Sep 2020 22:19:31

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 08:41:20**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-20T17:19:19', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'faa3493a-322c-48bc-a8ec-838d3bb2d71f' User entered 'None (0)'	System	20 Sep 2020 22:19:31
	System	20 Sep 2020 22:19:31

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 08:41:20**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-20T17:19:21', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'faa3493a-322c-48bc-a8ec-838d3bb2d71f'	System	20 Sep 2020 22:19:31
User entered 'None (0)'	System	20 Sep 2020 22:19:31

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 08:41:20**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-20T17:19:23', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'faa3493a-322c-48bc-a8ec-838d3bb2d71f' User entered 'None (0)'	System	20 Sep 2020 22:19:31

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-20T17:19:26', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'faa3493a-322c-48bc-a8ec-838d3bb2d71f'	System	20 Sep 2020 22:19:31
User entered 'No (N)'	System	20 Sep 2020 22:19:31

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-20T17:19:28', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'faa3493a-322c-48bc-a8ec-838d3bb2d71f' User entered '20 Sep 2020 17:19'	System	20 Sep 2020 22:19:31
	System	20 Sep 2020 22:19:31



**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 14:33:12
User entered 'Day 7'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 08:41:20**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-21T20:42:03', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'e10f5329-863a-4b89-9f46-ace34575537f'	System	22 Sep 2020 01:42:27
User entered 'None (0)'	System	22 Sep 2020 01:42:27

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 08:41:20**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-21T20:42:06', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'e10f5329-863a-4b89-9f46-ace34575537f'	System	22 Sep 2020 01:42:27
User entered 'None (0)'	System	22 Sep 2020 01:42:27

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 08:41:20**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-21T20:42:10', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'e10f5329-863a-4b89-9f46-ace34575537f'	System	22 Sep 2020 01:42:27
User entered 'None (0)'	System	22 Sep 2020 01:42:27

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 08:41:20**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-21T20:42:13', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'e10f5329-863a-4b89-9f46-ace34575537f'	System	22 Sep 2020 01:42:27
User entered 'None (0)'	System	22 Sep 2020 01:42:27

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 08:41:20**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-21T20:42:16', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'e10f5329-863a-4b89-9f46-ace34575537f'	System	22 Sep 2020 01:42:27
User entered 'None (0)'	System	22 Sep 2020 01:42:27



**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 08:41:20**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-21T20:42:18', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'e10f5329-863a-4b89-9f46-ace34575537f'	System	22 Sep 2020 01:42:27
User entered 'None (0)'	System	22 Sep 2020 01:42:27

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-21T20:42:21', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'e10f5329-863a-4b89-9f46-ace34575537f'	System	22 Sep 2020 01:42:27
User entered 'No (N)'	System	22 Sep 2020 01:42:27

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-09-21T20:42:24', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'e10f5329-863a-4b89-9f46-ace34575537f'	System	22 Sep 2020 01:42:27
User entered '21 Sep 2020 20:42'	System	22 Sep 2020 01:42:27

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 08:41:20**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 14:33:12

**US3002302**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:41:20**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	23 Sep 2020 22:51:44

**US3002302**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Jessica Satorie (b) (4) (b) (4)	23 Sep 2020 22:51:44

**US3002302**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:41:20**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Jessica Satorie (b) (4) (b) (4)	23 Sep 2020 22:51:44



**US3002302**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:41:20**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	23 Sep 2020 22:51:44

**US3002302**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:41:20**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	23 Sep 2020 22:51:50

**US3002302**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:41:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Sep 2020 22:51:50

**US3002302**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:41:20**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 21:36:35

**US3002302**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered '02 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 21:36:35

**US3002302**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:41:20**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 21:36:35

**US3002302**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:41:20**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 21:36:35

**US3002302**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:41:20**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 21:36:41



**US3002302**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:41:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Nov 2020 21:36:41

**US3002302**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:41:20**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 21:37:03

**US3002302**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered '09 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 21:37:03

**US3002302**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:41:20**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 21:37:03

**US3002302**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:41:20**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 21:37:03

**US3002302**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:41:20**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 21:37:08

**US3002302**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:41:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Nov 2020 21:37:08

US3002302

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:41:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please complete the rest of the forms in this folder as these are not to remain empty. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 05:47:36
Query 'Per CDM: Please complete the rest of the forms in this folder as these are not to remain empty. Thank you. ' answered with 'Subject did not have visit 2 due to convalescent period. Visit will be skipped.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 20:03:39
User opened query 'Per CDM: Please complete the rest of the forms in this folder as these are not to remain empty. Thank you. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 13:15:54
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 21:37:15



US3002302

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 21:37:15

US3002302

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 21:37:15

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:41:20**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	04 Nov 2020 21:37:15

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:20

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:03:47

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:03:47

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:03:47



US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:03:47

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:20

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:03:47

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:03:47

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:03:47



**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:41:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:03:47

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:03:47

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:03:47

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:03:47

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:03:47



US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:03:47

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:20

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:20

Pulse (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:03:47

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:03:47

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:03:47



**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:41:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:03:47

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:41:20

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 20:03:53

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 08:41:20**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:03:53

US3002302

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:41:20

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 20:04:06

US3002302

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:41:20

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:04:06

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 08:41:20**

[Test performed](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:04:06



**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 08:41:20**

[Result](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:04:06

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 08:41:20**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 20:04:06

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 08:41:20**

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:04:06

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 08:41:20**

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:04:06

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:04:06

US3002302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:41:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 20:04:16

US3002302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:41:20

[If No, reason not given](#)

Audit	User	Time (GMT)
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).		18 Nov 2020 20:05:02
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 20:05:02
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	18 Nov 2020 20:04:16
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:04:16

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered 'Visit 2 was skipped due to convalescent period.' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 20:05:02
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:04:16



**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 08:41:20**

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:04:16

US3002302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:41:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:04:16

US3002302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:04:16

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 08:41:20**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:04:16

US3002302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:41:20

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:04:16

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 08:41:20**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:04:16

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 08:41:20**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:04:16

US3002302

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:41:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 20:05:07



**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 08:41:20**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:05:07

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 08:41:20**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:05:07

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:05:07

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 26 Nov 2020 08:41:20**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:05:13

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	18 Nov 2020 20:05:13

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 20:05:13

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:05:13

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:05:13



**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	18 Nov 2020 20:05:13

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 20:05:13

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 08:41:20**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:05:13

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:05:13

US3002302

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:44:01

**US3002302**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:41:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Nov 2020 22:44:01

**US3002302**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:41:20**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:44:17

**US3002302**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:44:17



**US3002302**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:41:20**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:44:17

**US3002302**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:41:20**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:44:17

**US3002302**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:41:20**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:44:23

**US3002302**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:41:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Nov 2020 22:44:23

**US3002302**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:41:20**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:44:29

**US3002302**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:44:29

**US3002302**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:41:20**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:44:29

**US3002302**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:41:20**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:44:29



**US3002302**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:41:20**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:44:33

**US3002302**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:41:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Nov 2020 22:44:33

**US3002302**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:41:20**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:44:41

**US3002302**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:44:41

**US3002302**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:41:20**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:44:41

**US3002302**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:41:20**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:44:41

US3002302

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:44:45

**US3002302**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:41:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Nov 2020 22:44:45



**US3002302**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:41:20**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:44:56

**US3002302**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered '05 Nov 2020'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:44:56

**US3002302**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:44:56

**US3002302**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:41:20**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	05 Nov 2020 22:44:56

**US3002302**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:45:26

**US3002302**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '05 Nov 2020'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:45:26

**US3002302**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered '08:28'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:45:26

**US3002302**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered '05 Nov 2020 08:28'	System	05 Nov 2020 22:45:26



US3002302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:45:26

**US3002302**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:45:26

**US3002302**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:45:26

**US3002302**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '77'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:45:26

**US3002302**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Nov 2020 22:45:26

US3002302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:20

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

Audit	User	Time (GMT)
User entered '12'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:45:26

**US3002302**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Nov 2020 22:45:26

US3002302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '130'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:45:26



**US3002302**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Nov 2020 22:45:26

US3002302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '90'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:45:26

**US3002302**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Nov 2020 22:45:26

US3002302

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:41:20

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:45:36

US3002302

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:41:20

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '05 Nov 2020'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:45:36

**US3002302**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 08:41:20**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:45:52

**US3002302**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 08:41:20**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '05 Nov 2020'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:45:52

**US3002302**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 08:41:20**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '09:14'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:45:52



**US3002302**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 08:41:20**

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

Audit	User	Time (GMT)
User entered '05 Nov 2020 09:14'	System	05 Nov 2020 22:45:52

US3002302

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:41:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:45:56

**US3002302**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:41:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Nov 2020 22:45:56

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 14:33:12
User entered 'Day 64'	System	15 Sep 2020 14:33:12

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[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 (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-11-15T00:01:45', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '88837e33-db4a-4cf3-96a7-37471d65e2ba' User entered 'No (N)'	System	15 Nov 2020 06:02:11
	System	15 Nov 2020 06:02:11

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

Have you been exposed to someone with 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 (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-11-15T00:01:57', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '88837e33-db4a-4cf3-96a7-37471d65e2ba' User entered 'No (N)'	System	15 Nov 2020 06:02:11
	System	15 Nov 2020 06:02:11

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-11-15T00:02:02', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '88837e33-db4a-4cf3-96a7-37471d65e2ba' User entered '15 Nov 2020 00:02:02'	System	15 Nov 2020 06:02:11
	System	15 Nov 2020 06:02:11

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 14:33:12
User entered '15 Nov 2020 00:01'	System	15 Sep 2020 14:33:12



**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 14:33:12
User entered '19 Nov 2020 23:59'	System	15 Sep 2020 14:33:12

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '12 Nov 2020 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '16 Nov 2020 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[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 (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-11-21T15:31:29', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '65ea3e4a-32d5-430f-9676-8c4f3443a99a' User entered 'No (N)'	System	21 Nov 2020 21:31:41
	System	21 Nov 2020 21:31:41

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Have you been exposed to someone with 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 (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-11-21T15:31:37', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '65ea3e4a-32d5-430f-9676-8c4f3443a99a' User entered 'No (N)'	System	21 Nov 2020 21:31:41

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2020-11-21T15:31:40', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '65ea3e4a-32d5-430f-9676-8c4f3443a99a' User entered '21 Nov 2020 15:31:40'	System	21 Nov 2020 21:31:41
	System	21 Nov 2020 21:31:41



**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 08:34:23



**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 08:34:23



**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 08:34:23



**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 08:34:23



**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 08:34:23



**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 08:34:23



**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 08:34:23



**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 08:34:23



**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 08:34:23



**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 08:34:23



**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 08:34:23



**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 08:34:23



**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '17 Nov 2022 00:01'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:41:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:34:23
Amendment Manager: User entered '21 Nov 2022 23:59'	System	20 Nov 2020 08:34:23

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 08:41:20**

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:20
User entered '09 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:51:57

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 08:41:20**

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:20
User entered '14:31'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:51:57

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 08:41:20**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 14:31'	System	14 Oct 2020 22:51:57

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 08:41:20**

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:20
User entered 'Safety Call (Safety Call)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:51:57

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 08:41:20**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:20
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:51:57

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 08:41:20

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:53:16



US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 08:41:20

[Date](#)

Audit	User	Time (GMT)
User closed query 'Per ETRTR: Please add Symptoms entries since onset of COVID-19 Symptoms (per AE CRF, onset was 07Oct20), thanks.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 00:51:55
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
Query 'Per ETRTR: Please add Symptoms entries since onset of COVID-19 Symptoms (per AE CRF, onset was 07Oct20), thanks.' answered with 'updated' (Site from CRA).	Jessica Satorie (b) (4)	04 Nov 2020 18:52:07
User entered '07 Oct 2020' reason for change: Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 18:49:24
User opened query 'Per ETRTR: Please add Symptoms entries since onset of COVID-19 Symptoms (per AE CRF, onset was 07Oct20), thanks.' (Site from CRA).	(b) (4), (b) (6)	16 Oct 2020 19:14:55
User entered '14 Oct 2020'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '1' reason for change: Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 18:51:50
User entered '0'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 08:41:20

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty; reason for change Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 18:51:50
User entered '99'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 08:41:20**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 18:51:50
User entered '%'	System	14 Oct 2020 22:53:16

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 08:41:20

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty; reason for change Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 18:51:50
User entered '36.9' C	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 08:41:20

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty; reason for change Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 18:51:50
User entered 'None (None)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 08:41:20

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty; reason for change Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 18:51:50
User entered 'Mild (Mild)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 08:41:20

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty; reason for change Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 18:51:50
User entered 'None (None)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16



US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 08:41:20

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty; reason for change Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 18:51:50
User entered 'None (None)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 08:41:20

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty; reason for change Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 18:51:50
User entered 'None (None)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 08:41:20

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty; reason for change Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 18:51:50
User entered 'None (None)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 08:41:20

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty; reason for change Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 18:51:50
User entered 'None (None)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 08:41:20

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty; reason for change Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 18:51:50
User entered 'Moderate (Moderate)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 08:41:20

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty; reason for change Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 18:51:50
User entered 'None (None)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 08:41:20

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty; reason for change Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 18:51:50
User entered 'None (None)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 08:41:20

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty; reason for change Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 18:51:50
User entered 'Mild (Mild)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16



US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 08:41:20

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty; reason for change Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 18:51:50
User entered 'None (None)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 08:41:20

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty; reason for change Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 18:51:50
User entered 'None (None)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 08:41:20

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty; reason for change Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 18:51:50
User entered 'None (None)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 08:41:20

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty; reason for change Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 18:51:50
User entered 'None (None)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 08:41:20

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty; reason for change Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 18:51:50
User entered 'None (None)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 08:41:20

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:52:21

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '08 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:52:21

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'I'	Jessica Satorie (b) (4)	04 Nov 2020 18:52:21
	(b) (4)	



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**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 08:41:20**

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:52:21

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 08:41:20**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 18:52:21

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:52:21

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 08:41:20

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:52:21

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 08:41:20

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:52:21

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 08:41:20

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:52:21

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 08:41:20

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:52:21

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 08:41:20

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:52:21



US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 08:41:20

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:52:21

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 08:41:20

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:52:21

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 08:41:20

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:52:21

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 08:41:20

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:52:21

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 08:41:20**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:52:21

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:52:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 08:41:20

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:52:21

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:52:21



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 08:41:20

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:52:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 08:41:20

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:52:21

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 08:41:20

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:52:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 08:41:20

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:54:28

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 08:41:20**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '09 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:54:28

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 08:41:20**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '0'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:54:28

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 08:41:20**

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '99'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:54:28

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**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 08:41:20**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	04 Nov 2020 18:54:28



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 08:41:20

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '36.9' C	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:54:28

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 08:41:20

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:54:28

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 08:41:20

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'Mild (Mild)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:54:28

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 08:41:20**

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:54:28

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 08:41:20

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:54:28

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 08:41:20**

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:54:28

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 08:41:20

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:54:28

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 08:41:20

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:54:28



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 08:41:20

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'Moderate (Moderate)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:54:28

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 08:41:20**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:54:28

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 08:41:20**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:54:28
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 08:41:20

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'Mild (Mild)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:54:28

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 08:41:20

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:54:28

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 08:41:20**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:54:28

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 08:41:20

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:54:28
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 08:41:20

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:54:28



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 08:41:20

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:54:28
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 08:41:20

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:55:24

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 08:41:20**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '10 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:55:24

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 08:41:20

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '0'	Jessica Satorie (b) (4)	04 Nov 2020 18:55:24
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 08:41:20

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '99'	Jessica Satorie (b) (4)	04 Nov 2020 18:55:24
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 08:41:20**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	04 Nov 2020 18:55:24

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 08:41:20

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '97.6' F	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:55:24

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 08:41:20**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:55:24



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 08:41:20

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:55:24
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 08:41:20

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:55:24
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 08:41:20

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:55:24

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 08:41:20

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:55:24
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 08:41:20

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:55:24

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 08:41:20

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:55:24

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 08:41:20

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:55:24
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 08:41:20

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:55:24



US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 08:41:20

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:55:24
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 08:41:20

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'Mild (Mild)'	Jessica Satorie (b) (4)	04 Nov 2020 18:55:24
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 08:41:20

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:55:24

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 08:41:20

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:55:24
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 08:41:20

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:55:24

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 08:41:20

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:55:24
	(b) (4)	

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 08:41:20**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:55:24

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 08:41:20

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:18



**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 08:41:20**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '11 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:18

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 08:41:20**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '0'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:18

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 08:41:20**

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '100'	Jessica Satorie (b) (4)	04 Nov 2020 18:56:18
	(b) (4)	

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 08:41:20**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	04 Nov 2020 18:56:18

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 08:41:20**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '98.1' F	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:18

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 08:41:20

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:18

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 08:41:20**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:18

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 08:41:20

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:18



US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 08:41:20

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:18

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 08:41:20

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:56:18

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 08:41:20

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:18

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 08:41:20**

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:56:18

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 08:41:20

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:18

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 08:41:20**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:18

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 08:41:20**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:56:18

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 08:41:20**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'Mild (Mild)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:18



**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 08:41:20**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:18

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 08:41:20**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:56:18

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 08:41:20**

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:18

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 08:41:20

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:18

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 08:41:20**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:56:18

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 08:41:20

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:44

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 08:41:20**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '12 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:44

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 08:41:20**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '0'	Jessica Satorie (b) (4)	04 Nov 2020 18:56:44
	(b) (4)	



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 08:41:20

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '99'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:44

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 08:41:20**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	04 Nov 2020 18:56:44

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 08:41:20**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '98.2' F	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:44

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 08:41:20**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:44

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 08:41:20

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:44

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 08:41:20**

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:56:44
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 08:41:20

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:44

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 08:41:20

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:44



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 08:41:20

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:44

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 08:41:20**

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:56:44

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 08:41:20

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:44

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 08:41:20**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:44

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 08:41:20

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:56:44
	(b) (4)	

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 08:41:20**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:44

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 08:41:20**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:56:44
	(b) (4)	

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 08:41:20**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:56:44
	(b) (4)	



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 08:41:20

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:56:44
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 08:41:20

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:44

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 08:41:20**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:56:44

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 08:41:20**

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:57:19

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 08:41:20**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '13 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:57:19

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 08:41:20**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '0'	Jessica Satorie (b) (4)	04 Nov 2020 18:57:19
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 08:41:20

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '98'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:57:19

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 08:41:20**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	04 Nov 2020 18:57:19



**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 08:41:20**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '97.1' F	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:57:19

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 08:41:20**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:57:19
	(b) (4)	

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 08:41:20**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:57:19

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 08:41:20**

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:57:19

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 08:41:20

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:57:19

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 08:41:20**

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:57:19

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 08:41:20

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:57:19

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 08:41:20

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:57:19
	(b) (4)	



US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 08:41:20

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:57:19

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 08:41:20**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:57:19

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 08:41:20**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:57:19

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 08:41:20**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:57:19
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 08:41:20

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:57:19

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 08:41:20**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:57:19

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 08:41:20

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:57:19
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 08:41:20

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:57:19
	(b) (4)	



**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 08:41:20**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:57:19

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 08:41:20

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:01

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 08:41:20**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '14 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:01

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 08:41:20**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '0'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:01

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 08:41:20

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '99'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:01

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 08:41:20**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	04 Nov 2020 18:58:01

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 08:41:20

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '97.8' F	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:01

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 08:41:20

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:01



US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 08:41:20

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'Mild (Mild)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:01

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 08:41:20

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:01

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 08:41:20**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:01

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 08:41:20

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:01

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 08:41:20

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:01

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 08:41:20**

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:58:01

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 08:41:20

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:01

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 08:41:20**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:58:01



**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 08:41:20**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:58:01

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 08:41:20**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:58:01

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 08:41:20

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:01

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 08:41:20**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:01

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 08:41:20

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:01

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 08:41:20**

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:58:01

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 08:41:20

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:01

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 08:41:20

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:40



**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 08:41:20**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '15 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:40

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 08:41:20**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '0'	Jessica Satorie (b) (4)	04 Nov 2020 18:58:40
	(b) (4)	

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 08:41:20**

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '99'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:40

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 08:41:20**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	04 Nov 2020 18:58:40

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 08:41:20**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '97.8' F	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:40

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 08:41:20**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:40

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 08:41:20

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:40

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 08:41:20

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:40



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 08:41:20

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:40

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 08:41:20

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:40

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 08:41:20**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:40

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 08:41:20**

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:58:40
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 08:41:20

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:40

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 08:41:20**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:40

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 08:41:20**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:40

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 08:41:20**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:58:40



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 08:41:20

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:40

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 08:41:20**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:58:40

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 08:41:20

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:58:40
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 08:41:20

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:58:40
	(b) (4)	

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 08:41:20**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:40

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 08:41:20

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:59:36

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 08:41:20**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '16 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:59:36

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 08:41:20**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '0'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:59:36



**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 08:41:20**

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '99'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:59:36

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 08:41:20**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	04 Nov 2020 18:59:36

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 08:41:20**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '97.3' F	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:59:36

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 08:41:20

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:59:36

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 08:41:20

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'Mild (Mild)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:59:36

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 08:41:20

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:59:36
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 08:41:20**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:59:36

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 08:41:20

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:59:36



**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 08:41:20**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:59:36

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 08:41:20**

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:59:36
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 08:41:20

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:59:36

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 08:41:20**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:59:36

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 08:41:20**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:59:36

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 08:41:20**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:59:36

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 08:41:20

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:59:36

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 08:41:20

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:59:36
	(b) (4)	



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 08:41:20

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:59:36

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 08:41:20

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:59:36

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 08:41:20**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:59:36

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 08:41:20

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:00:05

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 08:41:20

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '17 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:00:05

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 08:41:20**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '0'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:00:05

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 08:41:20**

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '99'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:00:05

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 08:41:20**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	04 Nov 2020 19:00:05



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 08:41:20

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '97.1' F	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:00:05

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 08:41:20

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:00:05

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 08:41:20

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:00:05

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 08:41:20

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:00:05
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 08:41:20

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:00:05

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 08:41:20

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:00:05

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 08:41:20

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:00:05

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**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 08:41:20**

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:00:05



**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 08:41:20**

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:00:05

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 08:41:20

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:00:05

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**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 08:41:20**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:00:05

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**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 08:41:20**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:00:05
	(b) (4)	

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 08:41:20

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:00:05

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**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 08:41:20**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:00:05

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 08:41:20

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:00:05
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 08:41:20

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:00:05



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Form: Symptom Log (11)

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[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:00:05
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 08:41:20

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:00:37

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 08:41:20

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '18 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:00:37

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 08:41:20**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '0'	Jessica Satorie (b) (4)	04 Nov 2020 19:00:37
	(b) (4)	

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Form: Symptom Log (12)

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[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '99'	Jessica Satorie (b) (4)	04 Nov 2020 19:00:37
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 08:41:20**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	04 Nov 2020 19:00:37

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 08:41:20**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '99.0' F	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:00:37

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 08:41:20

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:00:37
	(b) (4)	



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Form: Symptom Log (12)

Generated On: 26 Nov 2020 08:41:20

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:00:37

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 08:41:20

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:00:37

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 08:41:20

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:00:37
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 08:41:20

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:00:37

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 08:41:20

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:00:37

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 08:41:20

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:00:37
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 08:41:20

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:00:37

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 08:41:20**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:00:37



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**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 08:41:20**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:00:37

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 08:41:20**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:00:37
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 08:41:20

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:00:37

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 08:41:20

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:00:37

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 08:41:20

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:00:37
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 08:41:20

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:00:37
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 08:41:20

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:00:37
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 08:41:20

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:03:43



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**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 08:41:20**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '19 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:03:43

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 08:41:20

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '0'	Jessica Satorie (b) (4)	04 Nov 2020 19:03:43
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 08:41:20**

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '99'	Jessica Satorie (b) (4)	04 Nov 2020 19:03:43

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**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 08:41:20**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	04 Nov 2020 19:03:43

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 08:41:20

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '98.8' F	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:03:43

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 08:41:20

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:03:43

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 08:41:20

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:03:43
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 08:41:20

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:03:43
	(b) (4)	



US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 08:41:20

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:03:43

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 08:41:20

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:03:43

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 08:41:20

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:03:43

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 08:41:20

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:03:43
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 08:41:20

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:03:43
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 08:41:20

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:03:43

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 08:41:20**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:03:43

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 08:41:20**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:03:43
	(b) (4)	



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 08:41:20

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:03:43

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 08:41:20

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:03:43
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 08:41:20

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:03:43

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 08:41:20

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:03:43
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 08:41:20

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:03:43

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 08:41:20

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:04:37

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (14)**

**Generated On: 26 Nov 2020 08:41:20**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '20 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:04:37

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (14)**

**Generated On: 26 Nov 2020 08:41:20**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '0'	Jessica Satorie (b) (4)	04 Nov 2020 19:04:37
	(b) (4)	



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 08:41:20

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '98'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:04:37

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (14)**

**Generated On: 26 Nov 2020 08:41:20**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	04 Nov 2020 19:04:37

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 08:41:20

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '97.4' F	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:04:37

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 08:41:20

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:04:37

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 08:41:20

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:04:37

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 08:41:20

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:04:37
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 08:41:20

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:04:37
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 08:41:20

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:04:37



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 08:41:20

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:04:37

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 08:41:20

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:04:37
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 08:41:20

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:04:37

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 08:41:20

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:04:37

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 08:41:20

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:04:37
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (14)**

**Generated On: 26 Nov 2020 08:41:20**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:04:37
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 08:41:20

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:04:37

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 08:41:20

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:04:37



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 08:41:20

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:04:37

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 08:41:20

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:04:37

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 08:41:20

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:04:37
	(b) (4)	

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Form: Symptom Log (16)

Generated On: 26 Nov 2020 08:41:20

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 15 (Day 15)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:05:13

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**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (16)**

**Generated On: 26 Nov 2020 08:41:20**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '21 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:05:13

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**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (16)**

**Generated On: 26 Nov 2020 08:41:20**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '0'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:05:13

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Form: Symptom Log (16)

Generated On: 26 Nov 2020 08:41:20

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '98'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:13
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (16)**

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	04 Nov 2020 19:05:13



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**Form: Symptom Log (16)**

**Generated On: 26 Nov 2020 08:41:20**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '97.2' F	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:05:13

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 08:41:20

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:05:13

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 08:41:20

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:05:13

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 08:41:20

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:13
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 08:41:20

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:13

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 08:41:20

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:05:13

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 08:41:20

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:05:13

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 08:41:20

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:13
	(b) (4)	



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Form: Symptom Log (16)

Generated On: 26 Nov 2020 08:41:20

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:13
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 08:41:20

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:05:13

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**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (16)**

**Generated On: 26 Nov 2020 08:41:20**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:13

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (16)**

**Generated On: 26 Nov 2020 08:41:20**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:05:13

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 08:41:20

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:05:13

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**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (16)**

**Generated On: 26 Nov 2020 08:41:20**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:13

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 08:41:20

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:13
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 08:41:20

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:13
	(b) (4)	



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Form: Symptom Log (16)

Generated On: 26 Nov 2020 08:41:20

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:13

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Form: Symptom Log (17)

Generated On: 26 Nov 2020 08:41:20

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 16 (Day 16)' reason for change:	Jessica Satorie (b) (4)	05 Nov 2020 22:42:44
Data Entry Error	(b) (4)	
User entered 'Day 17 (Day 17)'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:53
	(b) (4)	

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Form: Symptom Log (17)

Generated On: 26 Nov 2020 08:41:20

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '22 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:05:53

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 08:41:20**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '0'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:53
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 08:41:20

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '98'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:05:53

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**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 08:41:20**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	04 Nov 2020 19:05:53

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 08:41:20**

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '97.9' F	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:05:53

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 08:41:20**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:53



**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 08:41:20**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:53
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 08:41:20

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:53
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 08:41:20

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:05:53

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 08:41:20

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:05:53

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 08:41:20**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:53
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 08:41:20

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:53
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 08:41:20

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:53
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 08:41:20

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:05:53



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**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 08:41:20**

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:53
	(b) (4)	

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 08:41:20**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:53

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 08:41:20

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:05:53

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 08:41:20**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:53
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 08:41:20

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:05:53

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 08:41:20**

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:53
	(b) (4)	

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Symptom Log (17)**

**Generated On: 26 Nov 2020 08:41:20**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:53
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 08:41:20

[Date of Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: Saliva: Samples dated 11OCT2020 and 13OCT2020 for Day 3 and Day 5 is reported under Illness visit in PPD central lab, however saliva log is not completed in EDC. Please complete, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 05:44:15
Query 'Per GCL Lab Recon: Saliva: Samples dated 11OCT2020 and 13OCT2020 for Day 3 and Day 5 is reported under Illness visit in PPD central lab, however saliva log is not completed in EDC. Please complete, else clarify. Thank you.' answered with 'updated saliva log' (Site from DM).	Jessica Satorie (b) (4)	04 Nov 2020 17:33:37
User opened query 'Per GCL Lab Recon: Saliva: Samples dated 11OCT2020 and 13OCT2020 for Day 3 and Day 5 is reported under Illness visit in PPD central lab, however saliva log is not completed in EDC. Please complete, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:06:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:38:06
User entered '09 Oct 2020'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:51



**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 08:41:20**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:38:08
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:53:51

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 08:41:20

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:38:10
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 07:13:56
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'confirmed positive' (Site from System).	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:03
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	14 Oct 2020 22:53:51
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:53:51

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 08:41:20**

[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:38:35
User entered '09 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:53:51

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Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 08:41:20

[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:38:33
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:53:51

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 08:41:20

[Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:53:51

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Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 08:41:20

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:38:30
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:53:51

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 08:41:20

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:53:51

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 08:41:20**

[CLIA Certified?](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:53:51



**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: COVID Diagnostic Test**

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 22:53:51

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 08:41:20

Did the subject have Respiratory Rates  $\geq$  30 per Minute?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:07
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 08:41:20

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 08:41:20**

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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Folder: Covid-19 Assessment 09 Oct 2020

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[Respiratory Rate](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 08:41:20

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 08:41:20**

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 08:41:20

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33



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[Heart Rate](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

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Did the subject have Oxygen Saturation of  $\text{SpO}_2 \leq 93\%$  on room air at sea level?

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 08:41:20**

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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Folder: Covid-19 Assessment 09 Oct 2020

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 08:41:20**

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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[End Date](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33



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[PaO2](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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Folder: Covid-19 Assessment 09 Oct 2020

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[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 08:41:20**

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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Generated On: 26 Nov 2020 08:41:20

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33



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Non-Invasive Ventilation?

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 08:41:20

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 08:41:20

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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[End Date](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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[ECMO?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 08:41:20

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33



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[End Date](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 08:41:20

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 08:41:20

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

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Evidence of Shock Requires  
Vasopressors

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 08:41:20

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 08:41:20

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 08:41:20

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 08:41:20

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 08:41:20

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 08:41:20

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 08:41:20**

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

**US3002302**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 08:41:20**

[Clinical Evidence](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 08:41:20

[Date of Assessment](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 08:41:20

[Radiographical Evidence](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33



US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 08:41:20

[Date of Assessment](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 08:41:20

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 08:41:20

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 08:41:20

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 08:41:20

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:27:42
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:38

**US3002302**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 17:33:23

**US3002302**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:56:52
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 17:33:23

**US3002302**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:56:52
User entered '11 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 17:33:23



**US3002302**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 17:33:23

**US3002302**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:56:52
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 17:33:23

**US3002302**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:56:52
User entered '13 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 17:33:23

**US3002302**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 26 Nov 2020 08:41:20**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 17:33:23

**US3002302**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 26 Nov 2020 08:41:20**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:56:52
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 17:33:23

**US3002302**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 26 Nov 2020 08:41:20**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:56:52
User entered '15 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 17:33:23

**US3002302**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 26 Nov 2020 08:41:20**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 17:33:23

**US3002302**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 26 Nov 2020 08:41:20**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:56:52
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 17:33:23



**US3002302**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 26 Nov 2020 08:41:20**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:56:52
User entered '17 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 17:33:23

**US3002302**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 26 Nov 2020 08:41:20**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 17:33:23

**US3002302**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 26 Nov 2020 08:41:20**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:56:52
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 17:33:23

**US3002302**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 26 Nov 2020 08:41:20**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:56:52
User entered '22 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 17:33:23

**US3002302**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 26 Nov 2020 08:41:20**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 17:33:23

US3002302

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 08:41:20

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29OCT2020 is reported under Illness visit Day 21 in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 11:37:50
User closed query 'Per CDM: Please confirm no Saliva Samples were collected for Days 21 and 28 or make all applicable updates.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 10:54:35
Query 'Per CDM: Please confirm no Saliva Samples were collected for Days 21 and 28 or make all applicable updates.' answered with 'patient did not return saliva sample for day 21. Nasal swab collected at day 28 instead of saliva' (Site from DM).	Jessica Satorie (b) (4) (b) (4)	09 Nov 2020 23:44:52
User opened query 'Per CDM: Please confirm no Saliva Samples were collected for Days 21 and 28 or make all applicable updates.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 10:13:45
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:56:52
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 17:33:23

**US3002302**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 26 Nov 2020 08:41:20**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:56:52
User entered empty.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 17:33:23

**US3002302**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 26 Nov 2020 08:41:20**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 17:33:23



**US3002302**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 26 Nov 2020 08:41:20**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:56:52
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 17:33:23

**US3002302**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 26 Nov 2020 08:41:20**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:56:52
User entered empty.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 17:33:23

US3002302

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:41:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Per ETRTR: Please complete data entry for Saliva Collection page, thanks.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 00:51:15
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:41
Query 'Per ETRTR: Please complete data entry for Saliva Collection page, thanks.' answered with 'updated saliva page' (Site from CRA).	Jessica Satorie (b) (4)	04 Nov 2020 17:33:59
User opened query 'Per ETRTR: Please complete data entry for Saliva Collection page, thanks.' (Site from CRA).	(b) (4), (b) (6)	16 Oct 2020 19:13:42
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	14 Oct 2020 22:56:33

**US3002302**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:41:20**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:41
User entered '09 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:56:33

**US3002302**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:41:20**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:41
User entered 'Clinic (Clinic)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:56:33

**US3002302**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:41:20**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	14 Oct 2020 22:56:33

**US3002302**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:58
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:57:29

**US3002302**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:58
User entered '09 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:57:29



**US3002302**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:58
User entered '15:29'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:57:29

**US3002302**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 15:29'	System	14 Oct 2020 22:57:29

**US3002302**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:58
User entered '157.4' cm	Jessica Satorie (b) (4)	14 Oct 2020 22:57:29
DataPoint set to visible.	(b) (4) System	14 Oct 2020 22:56:33

**US3002302**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:58
User entered '109.6' kg	Jessica Satorie (b) (4)	14 Oct 2020 22:57:29
DataPoint set to visible.	(b) (4) System	14 Oct 2020 22:56:33

US3002302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:20

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:58
User entered '36.9' C	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:57:29

**US3002302**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:58
User entered 'Oral (Oral)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:57:29

**US3002302**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:58
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:57:29

**US3002302**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:58
User entered '80'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:57:29



**US3002302**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Oct 2020 22:57:29

US3002302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:58
User entered '16'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:57:29

**US3002302**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Oct 2020 22:57:29

US3002302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:58
User entered '140'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:57:29

**US3002302**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Oct 2020 22:57:29

**US3002302**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:58
User entered '86'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:57:29

**US3002302**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Oct 2020 22:57:29

**US3002302**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 08:41:20**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:56:06
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:57:53



**US3002302**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 08:41:20**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:56:06
User entered '09 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:57:53

US3002302

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 08:41:20

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:56:21
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:58:06

**US3002302**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 26 Nov 2020 08:41:20**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:56:21
User entered '09 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:58:06

**US3002302**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:41:20**

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:31:48
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:18:47

**US3002302**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:41:20**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:31:48
User entered '05 Nov 2020'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:18:47

**US3002302**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:41:20**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:31:48
User entered 'Clinic (Clinic)'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:18:47

**US3002302**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:41:20**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	05 Nov 2020 22:18:47

US3002302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Query 'Per CDM: Vital signs for 5 Nov 2020, is reported for "Convalescence visit day 28" as well as Visit 3 Day 57 (5 Nov 2020), kindly review and update appropriately else clarify.' answered with 'data correct as entered. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 17:52:12
User opened query 'Per CDM: Vital signs for 5 Nov 2020, is reported for "Convalescence visit day 28" as well as Visit 3 Day 57 (5 Nov 2020), kindly review and update appropriately else clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 19:16:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:32:26
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:20:27



**US3002302**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:32:26
User entered '05 Nov 2020'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:20:27

**US3002302**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:32:26
User entered '08:28'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:20:27

**US3002302**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '05 Nov 2020 08:28'	System	05 Nov 2020 22:20:27

**US3002302**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:32:26
User entered '157.4' cm	Jessica Satorie (b) (4)	05 Nov 2020 22:20:27
DataPoint set to visible.	(b) (4) System	05 Nov 2020 22:18:47

**US3002302**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:32:26
User entered '45' kg	Jessica Satorie (b) (4)	05 Nov 2020 22:20:27
DataPoint set to visible.	(b) (4) System	05 Nov 2020 22:18:47

US3002302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:41:20

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:32:26
User entered '36.8' C	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:20:27

**US3002302**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:32:26
User entered 'Oral (Oral)'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:20:27

**US3002302**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:32:26
User entered empty.	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:20:27



**US3002302**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:32:26
User entered '77'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:20:27

**US3002302**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Nov 2020 22:20:27

**US3002302**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:32:26
User entered '12'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:20:27

**US3002302**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Nov 2020 22:20:27

**US3002302**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:32:26
User entered '130'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:20:27

**US3002302**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Nov 2020 22:20:27

**US3002302**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:32:26
User entered '90'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:20:27

**US3002302**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:41:20**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Nov 2020 22:20:27



**US3002302**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 08:41:20**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:32:35
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:20:41

**US3002302**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 08:41:20**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:32:35
User entered '05 Nov 2020'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:20:41

US3002302

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 08:41:20

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:32:45
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:20:56

**US3002302**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 26 Nov 2020 08:41:20**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:32:45
User entered '05 Nov 2020'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:20:56

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 26 Nov 2020 08:41:20**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessica Satorie (b) (4)	14 Oct 2020 22:58:26
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	15 Sep 2020 17:04:25

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:20

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Dental and oral soft tissue infections, PT: Tooth abscess, LLT: Tooth abscess - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 23:00:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 23:00:17
Data point term sent to Coder	System	14 Oct 2020 22:59:53
User entered 'Tooth Abcess'	Jessica Satorie (b) (4)	14 Oct 2020 22:59:43
	(b) (4)	

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43



**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered '20 Sep 2020'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:20

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	05 Nov 2020 22:16:10
User entered 'No (N)' reason for change: Data Entry Error	Jessica Satorie (b) (4)	05 Nov 2020 22:16:10
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	05 Nov 2020 22:16:02
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	14 Oct 2020 22:59:43

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered '27 Oct 2020' reason for change: Data Entry Error	Jessica Satorie (b) (4)	05 Nov 2020 22:16:02
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:59:43

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 22:59:43



**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered '0'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered '0'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered '0'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43



**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered '0'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered '0'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered '0'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 21:39:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Nov 2020 21:39:09
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 21:39:09
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 22:59:43
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 21:39:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Nov 2020 21:39:09
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 21:39:09
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 22:59:43
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 21:39:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Nov 2020 21:39:09
User entered 'None (NONE)' reason for change: Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 21:39:09
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 22:59:43
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:41:20

None

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Treatment required = NO. However, there is a ConProc recorded that matches this AE. Please review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 04:40:48
Query 'Per DM CLR: Treatment required = NO. However, there is a ConProc recorded that matches this AE. Please review and update eCRF as appropriate. ' answered with 'Updated' (Site from DM).	Jessica Satorie (b) (4) (b) (4)	19 Nov 2020 22:45:28
DataPoint Un-verified.	Jessica Satorie (b) (4) (b) (4)	19 Nov 2020 22:45:22
User entered '0' reason for change: Data Entry Error	Jessica Satorie (b) (4) (b) (4)	19 Nov 2020 22:45:22
User opened query 'Per DM CLR: Treatment required = NO. However, there is a ConProc recorded that matches this AE. Please review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 09:54:23
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered '1'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43



**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered '0'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Jessica Satorie (b) (4) (b) (4)	19 Nov 2020 22:45:22
User entered '1' reason for change: Data Entry Error	Jessica Satorie (b) (4) (b) (4)	19 Nov 2020 22:45:22
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered '0'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:16:02
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Oct 2020 22:59:43

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Oct 2020 22:59:43

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:41:20**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:30
User entered 'USA-US005-2020-mRNA-1273-P301000005'	System	15 Oct 2020 12:32:26
User entered 'New'	(b) (4), (b) (6)	15 Oct 2020 12:32:26



US3002302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:41:20

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 23:07:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 23:07:23
Data point term sent to Coder	System	14 Oct 2020 23:05:59
User entered 'Covid-19'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 23:05:12

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 23:05:12

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 23:05:12

US3002302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:41:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 23:05:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 23:05:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessica Satorie (b) (4)	14 Oct 2020 23:05:31
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 23:05:12
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 23:05:12

US3002302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:41:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User closed query 'PV Query: Please clarify event onset date. The date is listed as 07 Oct 2020, however, there are no symptoms or COVID test for that date. Please update as applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 23:16:42
Query 'PV Query: Please clarify event onset date. The date is listed as 07 Oct 2020, however, there are no symptoms or COVID test for that date. Please update as applicable.' answered with 'updating symptoms log. symptoms started prior to visit ' (Site from Safety).	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 17:34:48
User opened query 'PV Query: Please clarify event onset date. The date is listed as 07 Oct 2020, however, there are no symptoms or COVID test for that date. Please update as applicable.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 17:01:59
User entered '07 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 23:05:12

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 23:05:12

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:41:20**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 23:05:12

US3002302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:41:20

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	04 Nov 2020 17:36:46
User entered 'No (N)' reason for change: Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 17:36:46
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	04 Nov 2020 17:35:41
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	14 Oct 2020 23:05:12



US3002302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:41:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm the end date of 16 Oct 2020 as symptom of mild cough was reported on that date. End date should be when symptoms were resolved.' (Site from Safety).	(b) (4), (b) (6)	21 Nov 2020 16:22:29
Query 'PV Query: Please confirm the end date of 16 Oct 2020 as symptom of mild cough was reported on that date. End date should be when symptoms were resolved.' answered with 'updated' (Site from Safety).	Jessica Satorie (b) (4)	19 Nov 2020 22:22:59
DataPoint Un-verified.	Jessica Satorie (b) (4)	19 Nov 2020 22:22:51
User entered '17 Oct 2020' reason for change: Data Entry Error	Jessica Satorie (b) (4)	19 Nov 2020 22:22:51
User opened query 'PV Query: Please confirm the end date of 16 Oct 2020 as symptom of mild cough was reported on that date. End date should be when symptoms were resolved.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:33:12
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 23:16:47
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	04 Nov 2020 18:16:34
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	04 Nov 2020 18:16:34
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'updated' (Site from Safety).	Jessica Satorie (b) (4)	04 Nov 2020 17:36:59
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	04 Nov 2020 17:35:41
User entered '16 Oct 2020' reason for change: Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 17:35:41
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 17:01:02

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:41:20**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 23:05:12

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:41:20**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 23:05:12

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:41:20**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 23:05:12

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 23:05:12

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 23:05:12

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered '0'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 23:05:12

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered '0'	Jessica Satorie (b) (4)	14 Oct 2020 23:05:12



**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered '0'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 23:05:12

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 23:05:12

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 23:05:12

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 23:05:12

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 23:05:12

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered '0'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 23:05:12

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered '0'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 23:05:12

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered '0'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 23:05:12



**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered 'Not Related (NOT RELATED)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 23:05:12

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered 'Not Related (NOT RELATED)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 23:05:12

US3002302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:41:20

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 08:49:28
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 'Due to covid-19 which is the AE' (Site from System).	Jessica Satorie (b) (4)	09 Nov 2020 23:39:30
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	09 Nov 2020 23:38:52
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 09:46:58
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		04 Nov 2020 18:23:31
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 by data change (Site from System).	System	04 Nov 2020 18:23:31
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' answered with 'updated page' (Site from DM).	Jessica Satorie (b) (4)	04 Nov 2020 18:22:42

US3002302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:41:20

Action taken with investigational product

Audit	User	Time (GMT)
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	04 Nov 2020 18:21:33
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:21:57
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 23:12:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 23:12:01
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Jessica Satorie (b) (4)	14 Oct 2020 23:12:01
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 23:05:12
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 23:05:12

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:41:20**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered '0'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 23:05:12

US3002302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:41:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 11:15:06
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'UPDATED cm PAGE' (Site from DM).	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:26:11
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:22:04
User entered 'I'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 23:05:12

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered '0'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 23:05:12

US3002302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:41:20

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User closed query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 23:16:56
Query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Jessica Satorie (b) (4)	04 Nov 2020 18:26:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 18:16:34
User opened query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 17:01:18
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessica Satorie (b) (4)	14 Oct 2020 23:05:12



**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:41:20**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 23:05:12

US3002302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:41:20

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User closed query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 23:28:58
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)	05 Nov 2020 23:28:53
User closed query 'PV Query: Please provide symptoms for the onset date of 07 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 23:17:01
Query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' answered with 'Patient denies covid exposure' (Site from Safety).	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 21:38:26
User entered 'PATIENT STATED SINUS COLD/ PRESSURE, COUGHING, SORE THROAT AND DRAINAGE. Patient denied any exposure to COVID.' reason for change: Data Entry Error	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 21:38:14
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 'medication added to cm log' (Site from Safety).	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:48:58
User entered 'PATIENT STATED SINUS COLD/ PRESSURE, COUGHING, SORE THROAT AND DRAINAGE' reason for change: Data Entry Error	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:48:42
Query 'PV Query: Please provide symptoms for the onset date of 07 Oct 2020.' answered with 'updated' (Site from Safety).	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:28:11
User entered 'Patient stated sinus cold/ pressure, coughing, sore throat and drainage starting' reason for change: Data Entry Error	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:28:01

US3002302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:41:20

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of the Immunologic Assessment blood sample.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 19:23:59
User opened query 'PV Query: Please provide the results of the Immunologic Assessment blood sample.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 17:02:17
User opened query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 17:01:41
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)	21 Oct 2020 17:01:30
User opened query 'PV Query: Please provide symptoms for the onset date of 07 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 17:00:48
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 23:05:12

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Oct 2020 23:05:12

**US3002302**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Oct 2020 23:05:12

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 08:41:20

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
User closed query 'Per ETRTR: Please confirm and update accordingly whether Medication was dosed for AE COVID-19, thanks.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 01:23:17
Query 'Per ETRTR: Please confirm and update accordingly whether Medication was dosed for AE COVID-19, thanks.' answered with 'Sudafed PE taken for Covid 19' (Site from CRA).	Jessica Satorie (b) (4)	09 Nov 2020 23:38:29
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:26
User opened query 'Per ETRTR: Please confirm and update accordingly whether Medication was dosed for AE COVID-19, thanks.' (Site from CRA).	(b) (4), (b) (6)	16 Oct 2020 19:11:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 17:04:35

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:41:20

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE MAGNESIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE MAGNESIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 19:14:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 19:14:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE SODIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:06:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:06:49
Data point term sent to Coder User entered 'Nexium'	System (b) (4), (b) (6) (b) (4)	15 Sep 2020 17:06:25 15 Sep 2020 17:05:26

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:05:26



**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Gastroesophageal reflux disease'	(b) (4), (b) (6)	15 Sep 2020 17:05:26

US3002302

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	(b) (4), (b) (6)	15 Sep 2020 17:05:26

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:41:20

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Sep 2020 17:05:26

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 08:41:20**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:05:26

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:41:20

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	15 Sep 2020 17:05:26

US3002302

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 08:41:20**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:05:26

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Sep 2020 17:05:26

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 08:41:20**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:05:26



**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2019'	(b) (4), (b) (6)	15 Sep 2020 17:05:26

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:05:26

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 17:05:26

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 08:41:20**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:05:26

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:05:26

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 17:05:26

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 17:05:26

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 17:05:26



US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:41:20

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 20:50:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 20:50:43
Data point term sent to Coder	System	15 Sep 2020 17:06:25
User entered 'Aspirin'	(b) (4), (b) (6) (b) (4)	15 Sep 2020 17:06:15

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:06:15

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Right chronic ankle pain/generalize osteoarthritis'	(b) (4), (b) (6)	15 Sep 2020 17:06:15

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '200'	(b) (4), (b) (6)	15 Sep 2020 17:06:15

US3002302

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Sep 2020 17:06:15

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:41:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:06:15

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:41:20

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	15 Sep 2020 17:06:15

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 08:41:20**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:06:15



**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Sep 2020 17:06:15

US3002302

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 08:41:20**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:06:15

US3002302

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un May 2020'	(b) (4), (b) (6)	15 Sep 2020 17:06:15

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:06:15

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 17:06:15

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 08:41:20**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:06:15

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:41:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:06:15

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 17:06:15



**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 17:06:15

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 17:06:15

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:41:20

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PHENYLEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: SUDAFED PE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 14:36:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 14:36:45
Data point term sent to Coder	System	09 Nov 2020 23:37:48
User closed query 'For coding purposes, references indicate different formulations for SUDAFED. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' (Site from System).	System	09 Nov 2020 23:37:13
Query 'For coding purposes, references indicate different formulations for SUDAFED. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' answered with 'updated' (Site from System).	Jessica Satorie (b) (4)	09 Nov 2020 23:37:13
User entered 'SUDAFED PE (phenylephrine)' reason for change: Data Entry Error	Jessica Satorie (b) (4)	09 Nov 2020 23:37:05
User opened query 'For coding purposes, references indicate different formulations for SUDAFED. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' (Site from System).	Coder Import (b) (4)	06 Nov 2020 01:01:26
Data point term sent to Coder	System	04 Nov 2020 18:25:51
User entered 'SUDAFED'	Jessica Satorie (b) (4)	04 Nov 2020 18:25:21

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:41:20**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:25:21

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:41:20**

[Indication](#)

Audit	User	Time (GMT)
User entered 'COVID-19'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:25:21

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:41:20**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:25:21

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:41:20

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:25:21

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:41:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:25:21



US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:41:20

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:25:21

US3002302

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:41:20**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:25:21

US3002302

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:41:20**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:25:21

US3002302

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:41:20**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:25:21

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:41:20**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020' reason for change: Data Entry Error	Jessica Satorie (b) (4)	19 Nov 2020 16:16:29
User entered '07 Oct 2020'	Jessica Satorie (b) (4)	04 Nov 2020 18:25:21

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:41:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:25:21

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:41:20**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:25:21

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:41:20**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered '08 Oct 2020' reason for change: Data Entry Error	Jessica Satorie (b) (4)	19 Nov 2020 16:16:29
User entered '07 Oct 2020'	Jessica Satorie (b) (4)	04 Nov 2020 18:25:21



**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:41:20**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:25:21

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:41:20**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 18:25:21

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:41:20**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 18:25:21

**US3002302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:41:20**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 18:25:21

US3002302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 08:41:20

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:34:11
DataPoint Un-verified.	Jessica Satorie (b) (4)	05 Nov 2020 22:17:08
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	05 Nov 2020 22:17:08
DataPoint Verified.	Jessica Satorie (b) (4)	05 Nov 2020 17:58:00
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:04:31

**US3002302**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 08:41:20**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:34:23
User entered '27 Oct 2020'	Jessica Satorie (b) (4)	05 Nov 2020 22:17:37
	(b) (4)	

**US3002302**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:34:23
User entered 'Root canal'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:17:37

**US3002302**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:34:23
User entered 'Adverse Event (AE)'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:17:37



**US3002302**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 08:41:20**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:34:23
User entered empty.	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:17:37

**US3002302**

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 26 Nov 2020 08:41:20**

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:21:33

US3002302

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 08:41:20

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: As per the CCG page no. 43(V2.0), Due to SARS CoV-2 can be selected as primary reason from list. Please review, reconcile and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 10:15:33
Query 'Per CDM: As per the CCG page no. 43(V2.0), Due to SARS CoV-2 can be selected as primary reason from list. Please review, reconcile and update accordingly. Thank you.' answered with 'updated' (Site from DM).	Jessica Satorie (b) (4)	09 Nov 2020 23:39:00
User entered 'Due to SARS-COV-2 (COVID)' reason for change: Data Entry Error	(b) (4)	09 Nov 2020 23:38:52
User opened query 'Per CDM: As per the CCG page no. 43(V2.0), Due to SARS CoV-2 can be selected as primary reason from list. Please review, reconcile and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 12:29:56
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 18:23:31
User entered 'Due to SARS-COV-2 (COVID)'	Jessica Satorie (b) (4)	04 Nov 2020 18:21:33

US3002302

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 08:41:20

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	09 Nov 2020 23:39:05
User entered empty; reason for change Data Entry Error	Jessica Satorie (b) (4)	09 Nov 2020 23:39:05
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	09 Nov 2020 23:38:52
User entered 'COVID-19' reason for change: Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 18:23:31
User entered empty.	Jessica Satorie (b) (4)	04 Nov 2020 18:21:33

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'USA-US005-2020-MRNA-1273-P301000005'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26



**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'Brandon'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'Essink'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered '3319 N 107th'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'Omaha'	System	15 Oct 2020 12:32:26



**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered '68134'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 23:29:34
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
User entered 'US'	System	15 Oct 2020 12:32:53

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	21 Nov 2020 15:52:04
User entered '2'	System	05 Nov 2020 23:29:49
User entered '1'	System	15 Oct 2020 12:32:53

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'USA-US005-2020-MRNA-1273-P301000005'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26



**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'Brandon'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'Essink'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered '3319 N 107th'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'Omaha'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered '68134'	System	15 Oct 2020 12:32:26



**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 23:29:34
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
User entered 'US'	System	15 Oct 2020 12:32:53

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	21 Nov 2020 15:52:04
User entered '2'	System	05 Nov 2020 23:29:49
User entered '1'	System	15 Oct 2020 12:32:53

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (1)**

**Generated On: 26 Nov 2020 08:41:20**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
User entered '15/Oct/2020 12:32'	System	15 Oct 2020 12:32:53

US3002302

Folder: SAE USA-US005-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 08:41:20

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 23:29:34
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
User entered 'I'	(b) (4), (b) (6)	15 Oct 2020 12:32:53

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'USA-US005-2020-MRNA-1273-P301000005'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26



**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'Brandon'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'Essink'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered '3319 N 107th'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'Omaha'	System	15 Oct 2020 12:32:26



**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered '68134'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 23:29:34
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
User entered 'US'	System	15 Oct 2020 12:32:53

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	21 Nov 2020 15:52:04
User entered '2'	System	05 Nov 2020 23:29:49
User entered '1'	System	15 Oct 2020 12:32:53

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (2)**

**Generated On: 26 Nov 2020 08:41:20**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '05/Nov/2020 23:29'	System	05 Nov 2020 23:29:49

US3002302

Folder: SAE USA-US005-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 08:41:20

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	05 Nov 2020 23:29:49

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'USA-US005-2020-MRNA-1273-P301000005'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26



**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'No (N)'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'Brandon'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'Essink'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered '3319 N 107th'	System	15 Oct 2020 12:32:26



**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered 'Omaha'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:47
User entered '68134'	System	15 Oct 2020 12:32:26

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 23:29:34
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:05
User entered 'US'	System	15 Oct 2020 12:32:53

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:41:20**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	21 Nov 2020 15:52:04
User entered '2'	System	05 Nov 2020 23:29:49
User entered '1'	System	15 Oct 2020 12:32:53

**US3002302**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (3)**

**Generated On: 26 Nov 2020 08:41:20**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '21/Nov/2020 10:52'	System	21 Nov 2020 15:52:04

US3002302

Folder: SAE USA-US005-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 08:41:20

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	21 Nov 2020 15:52:04