

US3002302 (Prod: Meridian Clinical Research)

Generated By: KC Joubran

Generated On: 11 Aug 2021 21:51:22

All time stamps listed in this document are displayed in GMT

US3002302

Form: Participant Creation

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

Participant ID

US3002302

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

US3002302

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3002302

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

Were any significant conditions reported?

Yes ☒

No ☐

US3002302

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 25 Mar 2021 12:46:06

Generated On: 11 Aug 2021 21:51:22

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="radio"/> 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

US3002302

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 25 Mar 2021 12:46:06

Generated On: 11 Aug 2021 21:51:22

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)	

US3002302

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 25 Mar 2021 12:46:06

Generated On: 11 Aug 2021 21:51:22

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)	_____

US3002302

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 25 Mar 2021 12:46:06

Generated On: 11 Aug 2021 21:51:22

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)	_____

US3002302

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 25 Mar 2021 12:46:06

Generated On: 11 Aug 2021 21:51:22

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)

Data signed: (b) (4) 25 Mar 2021 12:46:06

Generated On: 11 Aug 2021 21:51:22

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)	

US3002302

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 25 Mar 2021 12:46:06

Generated On: 11 Aug 2021 21:51:22

Condition	MENORRHAGIA
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

US3002302

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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 ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3002302

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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.

US3002302

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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)	

US3002302

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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 ☒

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

Height	ND - Not Done
Weight	ND - Not Done

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

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: Temperature_Day(4)

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

Yes ☐

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: General_Day(3)

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 2223

EAB) (1725)

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

57 of 2223

EAB) (1725)

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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 ☒

PRODUCTION RELEASE (v12.003

61 of 2223

EAB) (1725)

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:51:22

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

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002302

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002302

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002302

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 12:48:55

Generated On: 11 Aug 2021 21:51:22

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)

Data signed: (b) (4) 15 Feb 2021 12:48:55

Generated On: 11 Aug 2021 21:51:22

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)

Data signed: (b) (4) 15 Feb 2021 12:48:55

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 12:48:55

Generated On: 11 Aug 2021 21:51:22

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

Data signed: (b) (4) 15 Feb 2021 12:48:55

Generated On: 11 Aug 2021 21:51:22

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

Data signed: (b) (4) 15 Feb 2021 12:48:55

Generated On: 11 Aug 2021 21:51:22

Was study treatment given? Yes ☐
No ☒

If No, reason not given

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

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

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3002302

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 12:48:55

Generated On: 11 Aug 2021 21:51:22

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

Data signed: (b) (4) 15 Feb 2021 12:48:55

Generated On: 11 Aug 2021 21:51:22

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

Data signed: (b) (4) 15 Feb 2021 12:48:55

Generated On: 11 Aug 2021 21:51:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002302

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002302

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002302

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002302

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 12:48:55

Generated On: 11 Aug 2021 21:51:22

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

Data signed: (b) (4) 15 Feb 2021 12:48:55

Generated On: 11 Aug 2021 21:51:22

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 NOV 2020
Time of assessment (00:00-23:59)	08:28 (24 HR)
Vital Signs Date and Time (derived)	05 NOV 2020 08:28
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)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3002302

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 12:48:55

Generated On: 11 Aug 2021 21:51:22

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

Data signed: (b) (4) 15 Feb 2021 12:48:55

Generated On: 11 Aug 2021 21:51:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

05 NOV 2020

Collection time (00:00-23:59)

09:14 (24 HR)

Collection date and time (derived)

05 NOV 2020 09:14

US3002302

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 12:48:55

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	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: 11 Aug 2021 21:51:22

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 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: 11 Aug 2021 21:51:22

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 NOV 2020 15:13:53
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 DEC 2020 19:39:55

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 DEC 2020 22:02:46

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 DEC 2020 16:22:58
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 19:47:40

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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 ☒

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

31 DEC 2020 07:04:00

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 JAN 2021 06:49:25
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 JAN 2021 12:00:38
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: 11 Aug 2021 21:51:22

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 07:08:46

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 11:35:50

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: 11 Aug 2021 21:51:22

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 FEB 2021 12:01:07
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 FEB 2021 11:10:20

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 12:51:13

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 FEB 2021 02:42:07
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 MAR 2021 06:48:20
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 MAR 2021 06:33:10
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 15:20:29

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 12:32:06

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 07:59:17

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: 11 Aug 2021 21:51:22

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 12:06:18

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 06:07:52

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: 11 Aug 2021 21:51:22

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 20:03:20

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: 11 Aug 2021 21:51:22

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 12:06:36

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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 <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: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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="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: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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°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: 11 Aug 2021 21:51:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 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: 11 Aug 2021 21:51:22

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 21:51:22

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 11 Aug 2021 21:51:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 11 Aug 2021 21:51:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 11 Aug 2021 21:51:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

Date and time of submission	
Patient Cloud Open Date & Time	20 JAN 2022 00:01
Patient Cloud Close Date & Time	24 JAN 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

Date and time of submission	
Patient Cloud Open Date & Time	17 FEB 2022 00:01
Patient Cloud Close Date & Time	21 FEB 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 11 Aug 2021 21:51:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT	DAY 551
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 21:51:22

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

Date and time of submission	
Patient Cloud Open Date & Time	14 JUL 2022 00:01
Patient Cloud Close Date & Time	18 JUL 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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°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: 11 Aug 2021 21:51:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 21:51:22

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 21:51:22

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2022 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 11 Aug 2021 21:51:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2022 23:59

US3002302

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 21:51:22

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 21:17:35

US3002302

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3002302

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002302

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 JAN 2021

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 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:13:43

Generated On: 11 Aug 2021 21:51:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002302

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:13:43

Generated On: 11 Aug 2021 21:51:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3002302

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:13:43

Generated On: 11 Aug 2021 21:51:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002302

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 12:46:06

Generated On: 11 Aug 2021 21:51:22

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 MAR 2021

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 179 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 12:46:06

Generated On: 11 Aug 2021 21:51:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002302

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 14 Apr 2021 19:58:41

Generated On: 11 Aug 2021 21:51:22

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

Visit date (dd MMM yyyy)	12 APR 2021
--------------------------	-------------

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

Folder OID	VISIT4
------------	--------

US3002302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Apr 2021 19:58:41

Generated On: 11 Aug 2021 21:51:22

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3002302

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Apr 2021 19:58:41

Generated On: 11 Aug 2021 21:51:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 APR 2021

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

US3002302

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Apr 2021 19:58:41

Generated On: 11 Aug 2021 21:51:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 APR 2021

Collection time (00:00-23:59)

13:23 (24 HR)

Collection date and time (derived)

12 APR 2021 13:23

US3002302

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 14 Apr 2021 19:58:41

Generated On: 11 Aug 2021 21:51:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002302

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

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 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

Symptom Day

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

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

Date	07 OCT 2020
------	-------------

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

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

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

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

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

294 of 2223

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

295 of 2223

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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"/>

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	08 OCT 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

298 of 2223

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

299 of 2223

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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"/>

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	09 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

302 of 2223

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

303 of 2223

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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"/>

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

306 of 2223

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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"/>

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

310 of 2223

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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"/>

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

314 of 2223

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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"/>

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

Date	13 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

318 of 2223

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

319 of 2223

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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"/>

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

Date	14 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

322 of 2223

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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"/>

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

Date	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"/>

PRODUCTION RELEASE (v12.003

326 of 2223

EAB) (1725)

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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"/>

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

330 of 2223

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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"/>

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

334 of 2223

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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"/>

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

Date	18 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

338 of 2223

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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"/>

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 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"/>

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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"/>

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

346 of 2223

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

347 of 2223

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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"/>

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

Date	21 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

350 of 2223

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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"/>

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

354 of 2223

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

PRODUCTION RELEASE (v12.003

EAB) (1725)

358 of 2223

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

Ventilator Support:

High-Flow Oxygen? Yes ☐ No ☒

Start Date

End Date

Non-Invasive Ventilation? Yes ☐ No ☒

Start Date

End Date

Mechanical Ventilation? Yes ☐ No ☒

Start Date

End Date

ECMO? Yes ☐ No ☒

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐ No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐ No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐ No ☒

Start Date

PRODUCTION RELEASE (v12.003

EAB) (1725)

359 of 2223

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 05 Mar 2021 18:27:11

Generated On: 11 Aug 2021 21:51:22

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3002302

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 05 Mar 2021 18:27:11

Generated On: 11 Aug 2021 21:51:22

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	Yes	29 OCT 2020
Day 28	No	

US3002302

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 12:48:40

Generated On: 11 Aug 2021 21:51:22

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

Data signed: (b) (4) 25 Mar 2021 12:46:06

Generated On: 11 Aug 2021 21:51:22

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
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

Data signed: (b) (4) 15 Feb 2021 12:48:40

Generated On: 11 Aug 2021 21:51:22

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

Data signed: (b) (4) 15 Feb 2021 12:48:40

Generated On: 11 Aug 2021 21:51:22

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

Data signed: (b) (4) 25 Mar 2021 12:46:06

Generated On: 11 Aug 2021 21:51:22

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

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 NOV 2020
Time of assessment (00:00-23:59)	08:28 (24 HR)
Vital Signs Date and Time (derived)	05 NOV 2020 08:28
Height (xxx.x)	157.4 cm
Weight (xxx.x)	45 kg
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)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3002302

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 17:13:43

Generated On: 11 Aug 2021 21:51:22

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

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

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

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

US3002302

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

Form: Unblinding

Data signed: (b) (4) 16 Mar 2021 12:53:14

Generated On: 11 Aug 2021 21:51:22

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

US3002302

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 17:13:43

Generated On: 11 Aug 2021 21:51:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 FEB 2021

Collection time (00:00-23:59)

08:20 (24 HR)

Collection date and time (derived)

22 FEB 2021 08:20

US3002302

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 17:13:43

Generated On: 11 Aug 2021 21:51:22

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 FEB 2021
Collection time (00:00 - 23:59)	08:26
Collection Date and Time (derived)	22 FEB 2021 08:26

US3002302

Folder: Unscheduled (1)

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 21:51:22

Visit Date	
Please check all assessments that apply for this visit	
Physical Exam	
Vital Signs	
Immunogenicity Assessment	
Pregnancy Test	

US3002302

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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)

Data signed: (b) (4) 01 May 2021 11:49:03

Generated On: 11 Aug 2021 21:51:22

AEID

Adverse event

TOOTH ABSCESS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

20 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

27 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

377 of 2223

EAB) (1725)

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 01 May 2021 11:49:03

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 01 May 2021 11:49:03

Generated On: 11 Aug 2021 21:51:22

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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

379 of 2223

US3002302

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 01 May 2021 11:49:03

Generated On: 11 Aug 2021 21:51:22

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	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
PRODUCTION RELEASE (v12.003 EAB) (1725)	
380 of 2223	

US3002302

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 01 May 2021 11:49:03

Generated On: 11 Aug 2021 21:51:22

Admitted to ICU Derived (CSA Programming Field Only)

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 01 May 2021 11:49:03

Generated On: 11 Aug 2021 21:51:22

AEID

Adverse event

IUD PERFORATION OF UTERINE
WALL

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

01 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

382 of 2223

EAB) (1725)

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 01 May 2021 11:49:03

Generated On: 11 Aug 2021 21:51:22

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

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

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)

Data signed: (b) (4) 25 Mar 2021 12:46:06

Generated On: 11 Aug 2021 21:51:22

Name of Medication NEXIUM

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

385 of 2223

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Mar 2021 12:46:06

Generated On: 11 Aug 2021 21:51:22

	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	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)

Data signed: (b) (4) 25 Mar 2021 12:46:06

Generated On: 11 Aug 2021 21:51:22

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication RIGHT CHRONIC ANKLE
PAIN/GENERALIZE
OSTEOARTHRITIS

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

387 of 2223

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Mar 2021 12:46:06

Generated On: 11 Aug 2021 21:51:22

	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)

Data signed: (b) (4) 25 Mar 2021 12:46:06

Generated On: 11 Aug 2021 21:51:22

Name of Medication SUDAFED PE SINUS PRESSURE
(PHENYLEPHRINE)

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

389 of 2223

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 25 Mar 2021 12:46:06

Generated On: 11 Aug 2021 21:51:22

	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)	08 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Mar 2021 12:46:06

Generated On: 11 Aug 2021 21:51:22

Name of Medication MEDROXYPROGESTERONE

Prophylaxis Yes ☒
No ☐

Indication ENDOMETRIAL HYPERPLASIA
PROPHYLAXIS

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

DAY 1-14 OF EACH MONTH

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

391 of 2223

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Mar 2021 12:46:06

Generated On: 11 Aug 2021 21:51:22

	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)		01 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3002302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 15 Feb 2021 12:48:39

Generated On: 11 Aug 2021 21:51:22

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3002302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 25 Mar 2021 12:46:06

Generated On: 11 Aug 2021 21:51:22

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
27 OCT 2020	ROOT CANAL	Adverse Event	
12 MAR 2021	IUD REMOVAL SURGERY	Adverse Event	

US3002302

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 15 Feb 2021 12:48:40

Generated On: 11 Aug 2021 21:51:22

Date of dosing discontinuation (dd MMM yyyy) 13 OCT 2020

Primary reason for dosing discontinuation

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

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

US3002302

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:51:22

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

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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)

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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)

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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)

Data signed: (b) (4) 15 Feb 2021 12:48:54

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'US3002302'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 13:29:31

US3002302

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:51:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:23
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:23
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:23
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:23
User entered 'SCRN'	System	15 Sep 2020 16:59:49

US3002302

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:51:22

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered 'YEARS'	System	15 Sep 2020 17:00:00

US3002302

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:51:22

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered '50'	System	15 Sep 2020 14:32:44

US3002302

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:51:22

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
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: 11 Aug 2021 21:51:22

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4)	06 Nov 2020 14:51:06
User entered 'I'	(b) (4), (b) (6)	15 Sep 2020 17:00:00

US3002302

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:51:22

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
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: 11 Aug 2021 21:51:22

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
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: 11 Aug 2021 21:51:22

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
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: 11 Aug 2021 21:51:22

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:51:15
User entered '15 Sep 2020'	Jessica Satorie (b) (4)	15 Sep 2020 14:32:44

US3002302

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered 'Sep 2020'	System	15 Sep 2020 14:32:44

US3002302

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered '2020'	System	15 Sep 2020 14:32:44

US3002302

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:51:22

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:51:15
User entered 'Amendment 3 (3)'	Jessica Satorie (b) (4)	15 Sep 2020 14:32:44

US3002302

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:51:15
User entered empty.	Jessica Satorie (b) (4)	15 Sep 2020 14:32:44

US3002302

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:51:22

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4)	06 Nov 2020 14:51:15
User entered empty.	Jessica Satorie (b) (4)	15 Sep 2020 14:32:44

US3002302

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:51:22

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 14:51:15
User entered 'No (N)'	Jessica Satorie (b) (4)	15 Sep 2020 14:32:44
	(b) (4)	

US3002302

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:51:22

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered 'I'	System	15 Sep 2020 14:32:48

US3002302

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	15 Sep 2020 14:32:48

US3002302

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 21:51:22

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:00:42

US3002302

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:51:22

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
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) (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, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4) (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) (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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'un UNK 1999'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:01:01

US3002302

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:51:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:01:01

US3002302

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:51:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:01:01

US3002302

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:51:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'un UNK 1999'	(b) (4), (b) (6)	15 Sep 2020 17:01:01

US3002302

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:51:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:01:01

US3002302

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:51:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered 'Jan 1999'	System	15 Sep 2020 17:01:01

US3002302

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:51:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered '1999'	System	15 Sep 2020 17:01:01

US3002302

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:51:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered 'Jan 1999'	System	15 Sep 2020 17:01:01

US3002302

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:51:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered '1999'	System	15 Sep 2020 17:01:01

US3002302

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:51:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:01:17

US3002302

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:51:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:01:17

US3002302

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:51:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:01:17

US3002302

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:51:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:01:17

US3002302

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:51:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:01:17

US3002302

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:51:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered 'Jan 2019'	System	15 Sep 2020 17:01:17

US3002302

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:51:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered '2019'	System	15 Sep 2020 17:01:17

US3002302

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:51:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered empty.	System	15 Sep 2020 17:01:17

US3002302

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:51:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered empty.	System	15 Sep 2020 17:01:17

US3002302

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:51:22

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
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)	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)	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)	15 Sep 2020 17:01:27

US3002302

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	15 Sep 2020 17:01:30
User entered 'Un UNK 2000' reason for change: Data Entry Error	System	15 Sep 2020 17:01:30
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	15 Sep 2020 17:01:27
User entered 'u UNK 2000' (non-conformant).	System	15 Sep 2020 17:01:27
	(b) (4), (b) (6)	15 Sep 2020 17:01:27

US3002302

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:51:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:01:27

US3002302

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:51:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:01:27

US3002302

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:51:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:01:27

US3002302

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:51:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:01:27

US3002302

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:51:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
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: 11 Aug 2021 21:51:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
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: 11 Aug 2021 21:51:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered empty.	System	15 Sep 2020 17:01:27

US3002302

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:51:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered empty.	System	15 Sep 2020 17:01:27

US3002302

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:51:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'un UNK 2015'	Jessica Satorie (b) (4)	23 Sep 2020 22:53:16

US3002302

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:51:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '0'	Jessica Satorie (b) (4)	23 Sep 2020 22:53:16

US3002302

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:51:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	23 Sep 2020 22:53:16

US3002302

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:51:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	Jessica Satorie (b) (4)	23 Sep 2020 22:53:16

US3002302

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:51:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '0'	Jessica Satorie (b) (4)	23 Sep 2020 22:53:16

US3002302

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:51:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered 'Jan 2015'	System	23 Sep 2020 22:53:16

US3002302

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:51:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered '2015'	System	23 Sep 2020 22:53:16

US3002302

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:51:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered empty.	System	23 Sep 2020 22:53:16

US3002302

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:51:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered empty.	System	23 Sep 2020 22:53:16

US3002302

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:51:22

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
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)	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)	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)	23 Sep 2020 22:53:43

US3002302

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'un May 2015'	Jessica Satorie (b) (4)	23 Sep 2020 22:53:43

US3002302

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:51:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '0'	Jessica Satorie (b) (4)	23 Sep 2020 22:53:43

US3002302

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:51:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	23 Sep 2020 22:53:43

US3002302

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:51:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	Jessica Satorie (b) (4)	23 Sep 2020 22:53:43

US3002302

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:51:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '0'	Jessica Satorie (b) (4)	23 Sep 2020 22:53:43

US3002302

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:51:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered 'May 2015'	System	23 Sep 2020 22:53:43

US3002302

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:51:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered '2015'	System	23 Sep 2020 22:53:43

US3002302

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:51:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered empty.	System	23 Sep 2020 22:53:43

US3002302

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:51:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered empty.	System	23 Sep 2020 22:53:43

US3002302

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:51:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
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)	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)	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)	23 Sep 2020 22:54:00

US3002302

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'un UNK 2015'	Jessica Satorie (b) (4)	23 Sep 2020 22:54:00

US3002302

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:51:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '0'	Jessica Satorie (b) (4)	23 Sep 2020 22:54:00

US3002302

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:51:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	23 Sep 2020 22:54:00

US3002302

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:51:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	Jessica Satorie (b) (4)	23 Sep 2020 22:54:00

US3002302

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:51:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '0'	Jessica Satorie (b) (4)	23 Sep 2020 22:54:00

US3002302

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:51:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered 'Jan 2015'	System	23 Sep 2020 22:54:00

US3002302

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:51:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered '2015'	System	23 Sep 2020 22:54:00

US3002302

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:51:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered empty.	System	23 Sep 2020 22:54:00

US3002302

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:51:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered empty.	System	23 Sep 2020 22:54:00

US3002302

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:51:22

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menorrhagia, LLT: Menorrhagia - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 22:11:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 22:11:43
Data point term sent to Coder	System	24 Mar 2021 22:10:43
User entered 'menorrhagia'	Kimberly Mueller (b) (4)	24 Mar 2021 22:10:37

US3002302

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
User entered 'un UNK 2011'	Kimberly Mueller (b) (4)	24 Mar 2021 22:10:37

US3002302

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:51:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
User entered '0'	Kimberly Mueller (b) (4)	24 Mar 2021 22:10:37

US3002302

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:51:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
User entered 'No (N)'	Kimberly Mueller (b) (4)	24 Mar 2021 22:10:37

US3002302

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:51:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
User entered 'un UNK 2012'	Kimberly Mueller (b) (4)	24 Mar 2021 22:10:37

US3002302

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:51:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
User entered '0'	Kimberly Mueller (b) (4)	24 Mar 2021 22:10:37

US3002302

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:51:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered 'Jan 2011'	System	24 Mar 2021 22:10:37

US3002302

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:51:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered '2011'	System	24 Mar 2021 22:10:37

US3002302

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:51:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered 'Jan 2012'	System	24 Mar 2021 22:10:37

US3002302

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:51:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered '2012'	System	24 Mar 2021 22:10:37

US3002302

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:23
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:01:56

US3002302

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:23
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:01:56

US3002302

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:23
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '08:41'	(b) (4), (b) (6)	15 Sep 2020 17:01:56

US3002302

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:23
User entered '15 Sep 2020 08:41'	System	15 Sep 2020 17:01:56

US3002302

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:23
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '157.4' cm	(b) (4) (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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:23
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '111.4' kg	(b) (4) (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: 11 Aug 2021 21:51:22

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:23
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: 11 Aug 2021 21:51:22

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:23
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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:23
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
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: 11 Aug 2021 21:51:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:23
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:01:56

US3002302

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:23
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:01:56

US3002302

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:23
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:01:56

US3002302

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:23
User entered 'bpm'	System	15 Sep 2020 17:01:56

US3002302

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:23
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
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: 11 Aug 2021 21:51:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:23
User entered 'breaths/min'	System	15 Sep 2020 17:01:56

US3002302

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:23
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:01:56

US3002302

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:23
User entered 'mmHg'	System	15 Sep 2020 17:01:56

US3002302

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:23
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:01:56

US3002302

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:23
User entered 'mmHg'	System	15 Sep 2020 17:01:56

US3002302

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:23

US3002302

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:23

US3002302

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:51:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:02:02

US3002302

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:51:22

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:02:02

US3002302

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:51:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:02:10

US3002302

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:51:22

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:02:10

US3002302

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:51:22

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:02:10

US3002302

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:51:22

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:02:10

US3002302

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:02:10

US3002302

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:51:22

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:02:10

US3002302

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:02:10

US3002302

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:51:22

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:02:10

US3002302

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:51:22

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:02:18

US3002302

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:51:22

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:02:18

US3002302

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:51:22

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Urine (URINE)'	(b) (4), (b) (6)	15 Sep 2020 17:02:18

US3002302

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:51:22

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:02:18

US3002302

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:51:22

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
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) (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: 11 Aug 2021 21:51:22

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:02:18

US3002302

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:51:22

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:02:18

US3002302

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:51:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User entered empty.	System	15 Sep 2020 17:02:18

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:51:22

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:51:22

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Merchandizer'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:51:22

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'I'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:51:22

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:51:22

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:28:20
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:00:24

US3002302

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:51:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'VISIT1'	System	15 Sep 2020 17:02:26

US3002302

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '15 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 14:09:18

US3002302

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '146300'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 14:09:18

US3002302

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 14:09:18

US3002302

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:02:38

US3002302

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:02:38

US3002302

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:02:38

US3002302

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:02:38

US3002302

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:51:22

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:02:38

US3002302

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (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: 11 Aug 2021 21:51:22

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:51:22

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:51:22

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:51:22

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
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: 11 Aug 2021 21:51:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '08:41'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '77'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'bpm'	System	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '14'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'breaths/min'	System	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '133'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'mmHg'	System	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '89'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'mmHg'	System	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:51:22

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:51:22

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
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: 11 Aug 2021 21:51:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '10:00'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '86'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'bpm'	System	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '16'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'breaths/min'	System	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '128'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'mmHg'	System	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '80'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'mmHg'	System	15 Sep 2020 17:03:21

US3002302

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:51:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:26

US3002302

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:51:22

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:26

US3002302

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:51:22

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:31

US3002302

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:51:22

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:31

US3002302

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:51:22

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:31

US3002302

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:51:22

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:31

US3002302

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:51:22

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	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: 11 Aug 2021 21:51:22

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:31

US3002302

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:51:22

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:31

US3002302

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:51:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered empty.	System	15 Sep 2020 17:03:31

US3002302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:51:22

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	15 Sep 2020 14:33:12

US3002302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:51:22

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	Jessica Satorie (b) (4)	15 Sep 2020 14:33:12

US3002302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	Jessica Satorie (b) (4)	15 Sep 2020 14:33:12

US3002302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:51:22

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'MRNA-1273 OR PLACEBO'	System	15 Sep 2020 14:33:12

US3002302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:51:22

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '15 Sep 2020'	Jessica Satorie (b) (4)	15 Sep 2020 14:33:12

US3002302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:51:22

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '09:27'	Jessica Satorie (b) (4)	15 Sep 2020 14:33:12

US3002302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:51:22

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered '15 Sep 2020 09:27'	System	15 Sep 2020 14:33:12

US3002302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:51:22

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Left Arm (LEFT ARM)'	Jessica Satorie (b) (4)	15 Sep 2020 14:33:12

US3002302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:51:22

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'ONCE'	System	15 Sep 2020 14:33:12

US3002302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:51:22

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'INTRAMUSCULAR'	System	15 Sep 2020 14:33:12

US3002302

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:51:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:49

US3002302

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:51:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:49

US3002302

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:51:22

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '08:54'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:03:49

US3002302

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:51:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
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: 11 Aug 2021 21:51:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:04:00

US3002302

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:51:22

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
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: 11 Aug 2021 21:51:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:04:00

US3002302

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:51:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '08:47'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:04:00

US3002302

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:51:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
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: 11 Aug 2021 21:51:22

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
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: 11 Aug 2021 21:51:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:04:00

US3002302

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:51:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:04:00

US3002302

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:51:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered empty.	System	15 Sep 2020 17:04:00

US3002302

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:04:19

US3002302

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'I'	System	15 Sep 2020 17:04:19

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered '98.2'	System	15 Sep 2020 14:56:22
	System	15 Sep 2020 14:56:22

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'No (N)'	System	15 Sep 2020 14:56:22
	System	15 Sep 2020 14:56:22

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:51:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered '15 Sep 2020 09:56'	System	15 Sep 2020 14:56:22
	System	15 Sep 2020 14:56:22

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:51:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'Yes (Y)'	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: 11 Aug 2021 21:51:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered '15 Sep 2020 19:37'	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: 11 Aug 2021 21:51:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:51:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:51:22

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:51:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:51:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'Yes (Y)'	System	18 Sep 2020 11:46:36
	System	18 Sep 2020 11:46:36

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:51:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered '97.7'	System	18 Sep 2020 11:46:36
	System	18 Sep 2020 11:46:36

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'No (N)'	System	18 Sep 2020 11:46:36
	System	18 Sep 2020 11:46:36

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:51:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered '18 Sep 2020 06:46'	System	18 Sep 2020 11:46:36
	System	18 Sep 2020 11:46:36

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:51:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'Yes (Y)'	System	19 Sep 2020 00:52:51
	System	19 Sep 2020 00:52:51

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:51:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered '97.0'	System	19 Sep 2020 00:52:51
	System	19 Sep 2020 00:52:51

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered '18 Sep 2020 19:52'	System	19 Sep 2020 00:52:51
	System	19 Sep 2020 00:52:51

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:51:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'Yes (Y)'	System	19 Sep 2020 23:07:59
	System	19 Sep 2020 23:07:59

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:51:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered '97.5'	System	19 Sep 2020 23:07:59
	System	19 Sep 2020 23:07:59

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered '19 Sep 2020 18:07'	System	19 Sep 2020 23:07:59
	System	19 Sep 2020 23:07:59

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:51:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered '97.9'	System	20 Sep 2020 22:20:15
	System	20 Sep 2020 22:20:15

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered '20 Sep 2020 17:20'	System	20 Sep 2020 22:20:15
	System	20 Sep 2020 22:20:15

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:51:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered '97.9'	System	22 Sep 2020 01:41:30
	System	22 Sep 2020 01:41:30

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'No (N)'	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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'No (N)'	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: 11 Aug 2021 21:51:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:51:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:51:22

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:51:22

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:51:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:51:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:51:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'No (N)'	System	18 Sep 2020 11:46:53
	System	18 Sep 2020 11:46:53

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'No (N)'	System	18 Sep 2020 11:46:53
	System	18 Sep 2020 11:46:53

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:51:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered '18 Sep 2020 06:46'	System	18 Sep 2020 11:46:53
	System	18 Sep 2020 11:46:53

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:51:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'No (N)'	System	19 Sep 2020 00:51:27
	System	19 Sep 2020 00:51:27

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'No (N)'	System	19 Sep 2020 00:51:27
	System	19 Sep 2020 00:51:27

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:51:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (1)'	System	19 Sep 2020 00:51:27
	System	19 Sep 2020 00:51:27

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:51:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered '18 Sep 2020 19:51'	System	19 Sep 2020 00:51:27
	System	19 Sep 2020 00:51:27

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:51:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (1)'	System	19 Sep 2020 23:07:32
	System	19 Sep 2020 23:07:32

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:51:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'No (N)'	System	19 Sep 2020 23:07:32
	System	19 Sep 2020 23:07:32

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'No (N)'	System	19 Sep 2020 23:07:32
	System	19 Sep 2020 23:07:32

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:51:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (1)'	System	19 Sep 2020 23:07:32
	System	19 Sep 2020 23:07:32

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:51:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered '19 Sep 2020 18:07'	System	19 Sep 2020 23:07:32
	System	19 Sep 2020 23:07:32

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:51:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'No (N)'	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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'No (N)'	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: 11 Aug 2021 21:51:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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'	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: 11 Aug 2021 21:51:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered '20 Sep 2020 17:19'	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: 11 Aug 2021 21:51:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	System	15 Sep 2020 14:57:28
	System	15 Sep 2020 14:57:28

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:51:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	System	15 Sep 2020 14:57:28
	System	15 Sep 2020 14:57:28

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:51:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	System	15 Sep 2020 14:57:28
	System	15 Sep 2020 14:57:28

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:51:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	System	15 Sep 2020 14:57:28
	System	15 Sep 2020 14:57:28

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'No (N)'	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: 11 Aug 2021 21:51:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:51:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:51:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:51:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:51:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:51:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:51:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:51:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	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: 11 Aug 2021 21:51:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	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: 11 Aug 2021 21:51:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	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: 11 Aug 2021 21:51:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	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: 11 Aug 2021 21:51:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	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: 11 Aug 2021 21:51:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'No (N)'	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: 11 Aug 2021 21:51:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	System	19 Sep 2020 00:51:00
	System	19 Sep 2020 00:51:00

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:51:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	System	19 Sep 2020 00:51:00
	System	19 Sep 2020 00:51:00

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:51:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	System	19 Sep 2020 00:51:00
	System	19 Sep 2020 00:51:00

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:51:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	System	19 Sep 2020 00:51:00
	System	19 Sep 2020 00:51:00

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:51:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	System	19 Sep 2020 00:51:00
	System	19 Sep 2020 00:51:00

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:51:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	System	19 Sep 2020 00:51:00
	System	19 Sep 2020 00:51:00

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'No (N)'	System	19 Sep 2020 00:51:00
	System	19 Sep 2020 00:51:00

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:51:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	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: 11 Aug 2021 21:51:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	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: 11 Aug 2021 21:51:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	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: 11 Aug 2021 21:51:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	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: 11 Aug 2021 21:51:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	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: 11 Aug 2021 21:51:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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
	System	19 Sep 2020 23:07:17

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:51:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' 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: 11 Aug 2021 21:51:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' 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: 11 Aug 2021 21:51:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' 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: 11 Aug 2021 21:51:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' 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: 11 Aug 2021 21:51:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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
	System	20 Sep 2020 22:19:31

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'No (N)'	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: 11 Aug 2021 21:51:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	System	22 Sep 2020 01:42:27
	System	22 Sep 2020 01:42:27

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:51:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	System	22 Sep 2020 01:42:27
	System	22 Sep 2020 01:42:27

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:51:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	System	22 Sep 2020 01:42:27
	System	22 Sep 2020 01:42:27

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:51:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	System	22 Sep 2020 01:42:27
	System	22 Sep 2020 01:42:27

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:51:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	System	22 Sep 2020 01:42:27
	System	22 Sep 2020 01:42:27

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:51:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'None (0)'	System	22 Sep 2020 01:42:27
	System	22 Sep 2020 01:42:27

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered 'No (N)'	System	22 Sep 2020 01:42:27
	System	22 Sep 2020 01:42:27

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:51:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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' User entered '21 Sep 2020 20:42'	System	22 Sep 2020 01:42:27
	System	22 Sep 2020 01:42:27

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:51:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	23 Sep 2020 22:51:44

US3002302

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '23 Sep 2020'	Jessica Satorie (b) (4)	23 Sep 2020 22:51:44

US3002302

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Contact Made (CONTACT MADE)'	Jessica Satorie (b) (4)	23 Sep 2020 22:51:44

US3002302

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	Jessica Satorie (b) (4)	23 Sep 2020 22:51:44

US3002302

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	23 Sep 2020 22:51:50

US3002302

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'I'	System	23 Sep 2020 22:51:50

US3002302

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	04 Nov 2020 21:36:35

US3002302

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '02 Oct 2020'	Jessica Satorie (b) (4)	04 Nov 2020 21:36:35

US3002302

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Contact Made (CONTACT MADE)'	Jessica Satorie (b) (4)	04 Nov 2020 21:36:35

US3002302

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	Jessica Satorie (b) (4)	04 Nov 2020 21:36:35

US3002302

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	04 Nov 2020 21:36:41

US3002302

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'I'	System	04 Nov 2020 21:36:41

US3002302

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	04 Nov 2020 21:37:03

US3002302

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '09 Oct 2020'	Jessica Satorie (b) (4)	04 Nov 2020 21:37:03

US3002302

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Contact Made (CONTACT MADE)'	Jessica Satorie (b) (4)	04 Nov 2020 21:37:03

US3002302

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	Jessica Satorie (b) (4)	04 Nov 2020 21:37:03

US3002302

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	04 Nov 2020 21:37:08

US3002302

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'I'	System	04 Nov 2020 21:37:08

US3002302

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:51:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
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)	
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)	19 Nov 2020 05:47:36
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)	18 Nov 2020 20:03:39
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 13:15:54
	Jessica Satorie (b) (4)	04 Nov 2020 21:37:15
	(b) (4)	

US3002302

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	Jessica Satorie (b) (4)	04 Nov 2020 21:37:15

US3002302

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	Jessica Satorie (b) (4)	04 Nov 2020 21:37:15

US3002302

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:51:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'VISIT2'	System	04 Nov 2020 21:37:15

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
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: 11 Aug 2021 21:51:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered empty.	System	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered empty.	System	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered empty.	System	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered empty.	System	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:51:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered empty.	System	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
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: 11 Aug 2021 21:51:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered empty.	System	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered empty.	System	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered empty.	System	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered empty.	System	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:51:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered empty.	System	18 Nov 2020 20:03:47

US3002302

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:51:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:03:53

US3002302

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:51:22

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:03:53

US3002302

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:51:22

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Dec 2020 07:11:42
User closed query 'Per CDM: Is the participant of childbearing potential=Yes, yet Was the pregnancy test performed =No. Per protocol female participants of childbearing potential should have a pregnancy test performed at Visit 2 Day 29. Please update as appropriate, else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 06:23:47
Query 'Data is required. Please complete.' answered with 'this visit was not conducted' (Site from System).	(b) (4), (b) (6)	02 Dec 2020 16:23:01
Query 'Per CDM: Is the participant of childbearing potential=Yes, yet Was the pregnancy test performed =No. Per protocol female participants of childbearing potential should have a pregnancy test performed at Visit 2 Day 29. Please update as appropriate, else clarify. Thank you. ' answered with 'this visit was not conducted' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 16:22:55
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 16:22:30
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 16:22:30
User opened query 'Per CDM: Is the participant of childbearing potential=Yes, yet Was the pregnancy test performed =No. Per protocol female participants of childbearing potential should have a pregnancy test performed at Visit 2 Day 29. Please update as appropriate, else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 13:02:47
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: 11 Aug 2021 21:51:22

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:04:06

US3002302

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:51:22

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:04:06

US3002302

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:51:22

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:04:06

US3002302

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:51:22

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty; reason for change Data Entry Error	(b) (4)	02 Dec 2020 16:23:04
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: 11 Aug 2021 21:51:22

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:04:06

US3002302

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:51:22

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:04:06

US3002302

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:51:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered empty.	System	18 Nov 2020 20:04:06

US3002302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:51:22

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:04:16

US3002302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:51:22

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Confirmed COVID-19 (COVID)' reason for change: Data Entry Error	(b) (4)	02 Dec 2020 16:24:12
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).	(b) (4), (b) (6)	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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User closed query 'Per CDM: Please review if the reason for treatment not given refers to Confirmed COVID-19 which is one of the options from the dropdown list provided. Kindly update as appropriate or clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 06:31:52
Query 'Per CDM: Please review if the reason for treatment not given refers to Confirmed COVID-19 which is one of the options from the dropdown list provided. Kindly update as appropriate or clarify. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 16:24:18
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 16:24:12
User opened query 'Per CDM: Please review if the reason for treatment not given refers to Confirmed COVID-19 which is one of the options from the dropdown list provided. Kindly update as appropriate or clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 08:17:42
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: 11 Aug 2021 21:51:22

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered empty.	System	18 Nov 2020 20:04:16

US3002302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:51:22

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:04:16

US3002302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:51:22

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:04:16

US3002302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:51:22

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered empty.	System	18 Nov 2020 20:04:16

US3002302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:51:22

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:04:16

US3002302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:51:22

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered empty.	System	18 Nov 2020 20:04:16

US3002302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:51:22

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered empty.	System	18 Nov 2020 20:04:16

US3002302

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:51:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:05:07

US3002302

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:51:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:05:07

US3002302

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:51:22

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:05:07

US3002302

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:51:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered empty.	System	18 Nov 2020 20:05:07

US3002302

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:51:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (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: 11 Aug 2021 21:51:22

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
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: 11 Aug 2021 21:51:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	(b) (4) (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: 11 Aug 2021 21:51:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (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: 11 Aug 2021 21:51:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
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: 11 Aug 2021 21:51:22

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
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: 11 Aug 2021 21:51:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	(b) (4) (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: 11 Aug 2021 21:51:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	(b) (4) (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: 11 Aug 2021 21:51:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered empty.	System	18 Nov 2020 20:05:13

US3002302

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	05 Nov 2020 22:44:01

US3002302

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'I'	System	05 Nov 2020 22:44:01

US3002302

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	Jessica Satorie (b) (4)	05 Nov 2020 22:44:17

US3002302

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	Jessica Satorie (b) (4)	05 Nov 2020 22:44:17

US3002302

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	Jessica Satorie (b) (4)	05 Nov 2020 22:44:17

US3002302

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	Jessica Satorie (b) (4)	05 Nov 2020 22:44:17

US3002302

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	05 Nov 2020 22:44:23

US3002302

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'I'	System	05 Nov 2020 22:44:23

US3002302

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	Jessica Satorie (b) (4)	05 Nov 2020 22:44:29

US3002302

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	Jessica Satorie (b) (4)	05 Nov 2020 22:44:29

US3002302

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	Jessica Satorie (b) (4)	05 Nov 2020 22:44:29

US3002302

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	Jessica Satorie (b) (4)	05 Nov 2020 22:44:29

US3002302

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	05 Nov 2020 22:44:33

US3002302

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'I'	System	05 Nov 2020 22:44:33

US3002302

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'No (N)'	Jessica Satorie (b) (4)	05 Nov 2020 22:44:41

US3002302

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	Jessica Satorie (b) (4)	05 Nov 2020 22:44:41

US3002302

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	Jessica Satorie (b) (4)	05 Nov 2020 22:44:41

US3002302

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	Jessica Satorie (b) (4)	05 Nov 2020 22:44:41

US3002302

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	05 Nov 2020 22:44:45

US3002302

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'I'	System	05 Nov 2020 22:44:45

US3002302

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:51:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	05 Nov 2020 22:44:56

US3002302

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '05 Nov 2020'	Jessica Satorie (b) (4)	05 Nov 2020 22:44:56

US3002302

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Clinic (Clinic)'	Jessica Satorie (b) (4)	05 Nov 2020 22:44:56

US3002302

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:51:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'VISIT3'	System	05 Nov 2020 22:44:56

US3002302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	05 Nov 2020 22:45:26

US3002302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '05 Nov 2020'	Jessica Satorie (b) (4)	05 Nov 2020 22:45:26

US3002302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '08:28'	Jessica Satorie (b) (4)	05 Nov 2020 22:45:26

US3002302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '36.8' C	Jessica Satorie (b) (4)	05 Nov 2020 22:45:26

US3002302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Oral (Oral)'	Jessica Satorie (b) (4)	05 Nov 2020 22:45:26

US3002302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	Jessica Satorie (b) (4)	05 Nov 2020 22:45:26

US3002302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '77'	Jessica Satorie (b) (4)	05 Nov 2020 22:45:26

US3002302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'bpm'	System	05 Nov 2020 22:45:26

US3002302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '12'	Jessica Satorie (b) (4)	05 Nov 2020 22:45:26

US3002302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'breaths/min'	System	05 Nov 2020 22:45:26

US3002302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '130'	Jessica Satorie (b) (4)	05 Nov 2020 22:45:26

US3002302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'mmHg'	System	05 Nov 2020 22:45:26

US3002302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '90'	Jessica Satorie (b) (4)	05 Nov 2020 22:45:26

US3002302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'mmHg'	System	05 Nov 2020 22:45:26

US3002302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17

US3002302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17

US3002302

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:51:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	05 Nov 2020 22:45:36

US3002302

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:51:22

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '05 Nov 2020'	Jessica Satorie (b) (4)	05 Nov 2020 22:45:36

US3002302

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:51:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	05 Nov 2020 22:45:52

US3002302

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:51:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '05 Nov 2020'	Jessica Satorie (b) (4)	05 Nov 2020 22:45:52

US3002302

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:51:22

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '09:14'	Jessica Satorie (b) (4)	05 Nov 2020 22:45:52

US3002302

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:51:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
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: 11 Aug 2021 21:51:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	05 Nov 2020 22:45:56

US3002302

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'I'	System	05 Nov 2020 22:45:56

US3002302

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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'	System	15 Nov 2020 06:02:11
User entered 'No (N)'	System	15 Nov 2020 06:02:11

US3002302

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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'	System	15 Nov 2020 06:02:11
User entered 'No (N)'	System	15 Nov 2020 06:02:11

US3002302

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:13:39
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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

Have you been exposed to someone with 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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: '2020-11-27T15:13:47', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'b992d888-edbf-4167-807a-08e89ff7b30b' User entered 'No (N)'	System	27 Nov 2020 21:13:54

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[Have you been exposed to someone with 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: '2020-11-27T15:13:50', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'b992d888-edbf-4167-807a-08e89ff7b30b' User entered 'No (N)'	System	27 Nov 2020 21:13:54

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: '2020-11-27T15:13:53', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'b992d888-edbf-4167-807a-08e89ff7b30b' User entered '27 Nov 2020 15:13:53'	System	27 Nov 2020 21:13:54
	System	27 Nov 2020 21:13:54

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: '2020-12-04T19:39:49', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '5730c0b6-9903-44e6-9198-b4f57492f7fc' User entered 'No (N)'	System	05 Dec 2020 01:39:57
	System	05 Dec 2020 01:39:57

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[Have you been exposed to someone with 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: '2020-12-04T19:39:52', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '5730c0b6-9903-44e6-9198-b4f57492f7fc' User entered 'No (N)'	System	05 Dec 2020 01:39:57

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: '2020-12-04T19:39:55', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '5730c0b6-9903-44e6-9198-b4f57492f7fc' User entered '04 Dec 2020 19:39:55'	System	05 Dec 2020 01:39:57
	System	05 Dec 2020 01:39:57

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: '2020-12-10T22:02:40', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'd7272519-6364-4b8b-888a-948fa91f567a' User entered 'No (N)'	System	11 Dec 2020 04:02:51
	System	11 Dec 2020 04:02:51

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

Have you been exposed to someone with 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: '2020-12-10T22:02:42', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'd7272519-6364-4b8b-888a-948fa91f567a' User entered 'No (N)'	System	11 Dec 2020 04:02:51
	System	11 Dec 2020 04:02:51

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: '2020-12-10T22:02:46', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'd7272519-6364-4b8b-888a-948fa91f567a' User entered '10 Dec 2020 22:02:46'	System	11 Dec 2020 04:02:51
	System	11 Dec 2020 04:02:51

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: '2020-12-18T16:22:52', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'cf233ec8-7a15-45f7-9bb0-be253549137b' User entered 'No (N)'	System	18 Dec 2020 22:23:02
	System	18 Dec 2020 22:23:02

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[Have you been exposed to someone with 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: '2020-12-18T16:22:55', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'cf233ec8-7a15-45f7-9bb0-be253549137b' User entered 'No (N)'	System	18 Dec 2020 22:23:02
	System	18 Dec 2020 22:23:02

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: '2020-12-18T16:22:58', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'cf233ec8-7a15-45f7-9bb0-be253549137b' User entered '18 Dec 2020 16:22:58'	System	18 Dec 2020 22:23:02
	System	18 Dec 2020 22:23:02

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: '2020-12-27T19:47:35', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '62eb91cb-91e1-40c4-a66d-f7f54da8b69c' User entered 'No (N)'	System	28 Dec 2020 01:47:42
	System	28 Dec 2020 01:47:42

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[Have you been exposed to someone with 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: '2020-12-27T19:47:37', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '62eb91cb-91e1-40c4-a66d-f7f54da8b69c' User entered 'No (N)'	System	28 Dec 2020 01:47:42
	System	28 Dec 2020 01:47:42

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: '2020-12-27T19:47:40', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '62eb91cb-91e1-40c4-a66d-f7f54da8b69c' User entered '27 Dec 2020 19:47:40'	System	28 Dec 2020 01:47:42
	System	28 Dec 2020 01:47:42

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: '2020-12-31T07:03:53', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '085ff68e-dc2d-45b9-b1cc-08331db0fb69' User entered 'No (N)'	System	31 Dec 2020 13:04:03
	System	31 Dec 2020 13:04:03

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[Have you been exposed to someone with 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: '2020-12-31T07:03:57', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '085ff68e-dc2d-45b9-b1cc-08331db0fb69'	System	31 Dec 2020 13:04:03
User entered 'No (N)'	System	31 Dec 2020 13:04:03

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: '2020-12-31T07:04:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '085ff68e-dc2d-45b9-b1cc-08331db0fb69' User entered '31 Dec 2020 07:04:00'	System	31 Dec 2020 13:04:03
	System	31 Dec 2020 13:04:03

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: '2021-01-11T06:49:20', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '854b3b65-050e-4c6c-8b94-f22113bfa51a' User entered 'No (N)'	System	11 Jan 2021 12:49:28
	System	11 Jan 2021 12:49:28

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[Have you been exposed to someone with 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: '2021-01-11T06:49:22', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '854b3b65-050e-4c6c-8b94-f22113bfa51a' User entered 'No (N)'	System	11 Jan 2021 12:49:28
	System	11 Jan 2021 12:49:28

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: '2021-01-11T06:49:25', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '854b3b65-050e-4c6c-8b94-f22113bfa51a' User entered '11 Jan 2021 06:49:25'	System	11 Jan 2021 12:49:28
	System	11 Jan 2021 12:49:28

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: '2021-01-16T12:00:31', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'b185b152-4313-4b16-9298-5ff33fcbcbfc' User entered 'No (N)'	System	16 Jan 2021 18:00:56
	System	16 Jan 2021 18:00:56

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

Have you been exposed to someone with 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: '2021-01-16T12:00:36', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'b185b152-4313-4b16-9298-5ff33fcbcbfc'	System	16 Jan 2021 18:00:56
User entered 'No (N)'	System	16 Jan 2021 18:00:56

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: '2021-01-16T12:00:38', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'b185b152-4313-4b16-9298-5ff33fcbcbfc' User entered '16 Jan 2021 12:00:38'	System	16 Jan 2021 18:00:56
	System	16 Jan 2021 18:00:56

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: '2021-01-21T07:08:39', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '90b07300-fcd0-486c-8102-08199d117c37'	System	21 Jan 2021 13:09:19
User entered 'No (N)'	System	21 Jan 2021 13:09:19

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

Have you been exposed to someone with 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: '2021-01-21T07:08:43', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '90b07300-fcd0-486c-8102-08199d117c37'	System	21 Jan 2021 13:09:19
User entered 'No (N)'	System	21 Jan 2021 13:09:19

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: '2021-01-21T07:08:46', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '90b07300-fcd0-486c-8102-08199d117c37' User entered '21 Jan 2021 07:08:46'	System	21 Jan 2021 13:09:19

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: '2021-01-29T11:35:45', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'f332070b-2de9-4c7a-8893-c0f24be6223f' User entered 'No (N)'	System	29 Jan 2021 17:35:56

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

Have you been exposed to someone with 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: '2021-01-29T11:35:48', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'f332070b-2de9-4c7a-8893-c0f24be6223f' User entered 'No (N)'	System	29 Jan 2021 17:35:56

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: '2021-01-29T11:35:50', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'f332070b-2de9-4c7a-8893-c0f24be6223f' User entered '29 Jan 2021 11:35:50'	System	29 Jan 2021 17:35:56
	System	29 Jan 2021 17:35:56

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: '2021-02-06T12:00:58', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '90228026-9273-4fac-a5b4-0b1850a0c95c' User entered 'No (N)'	System	06 Feb 2021 18:02:20
	System	06 Feb 2021 18:02:20

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

Have you been exposed to someone with 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: '2021-02-06T12:01:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '90228026-9273-4fac-a5b4-0b1850a0c95c' User entered 'No (N)'	System	06 Feb 2021 18:02:20
	System	06 Feb 2021 18:02:20

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: '2021-02-06T12:01:07', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '90228026-9273-4fac-a5b4-0b1850a0c95c' User entered '06 Feb 2021 12:01:07'	System	06 Feb 2021 18:02:20
	System	06 Feb 2021 18:02:20

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: '2021-02-11T11:10:16', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'effc2d35-dc2b-46cf-9a4d-ff650c7e20c9'	System	11 Feb 2021 17:16:56
User entered 'No (N)'	System	11 Feb 2021 17:16:56

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[Have you been exposed to someone with 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: '2021-02-11T11:10:18', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'effc2d35-dc2b-46cf-9a4d-ff650c7e20c9'	System	11 Feb 2021 17:16:56
User entered 'No (N)'	System	11 Feb 2021 17:16:56

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: '2021-02-11T11:10:20', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'effc2d35-dc2b-46cf-9a4d-ff650c7e20c9' User entered '11 Feb 2021 11:10:20'	System	11 Feb 2021 17:16:56
	System	11 Feb 2021 17:16:56

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: '2021-02-18T12:50:57', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'f8c17695-f8a0-4f96-a61d-7b81b578bebd' User entered 'No (N)'	System	18 Feb 2021 18:51:17
	System	18 Feb 2021 18:51:17

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

Have you been exposed to someone with 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: '2021-02-18T12:51:10', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'f8c17695-f8a0-4f96-a61d-7b81b578bebd' User entered 'No (N)'	System	18 Feb 2021 18:51:17

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: '2021-02-18T12:51:13', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'f8c17695-f8a0-4f96-a61d-7b81b578bebd' User entered '18 Feb 2021 12:51:13'	System	18 Feb 2021 18:51:17
	System	18 Feb 2021 18:51:17

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: '2021-02-26T20:41:59-06:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '58775856-d58b-4ee7-af4e-5b8b950eedee' User entered 'No (N)'	System	27 Feb 2021 02:50:52
	System	27 Feb 2021 02:50:52

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[Have you been exposed to someone with 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: '2021-02-26T20:42:04-06:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '58775856-d58b-4ee7-af4e-5b8b950eedee' User entered 'No (N)'	System	27 Feb 2021 02:50:52
	System	27 Feb 2021 02:50:52

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: '2021-02-26T20:42:07-06:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '58775856-d58b-4ee7-af4e-5b8b950eedee' User entered '27 Feb 2021 02:42:07'	System	27 Feb 2021 02:50:52
	System	27 Feb 2021 02:50:52

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: '2021-03-04T06:48:14-06:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'b02347d8-56c1-41e2-9e9f-4801c25719e0'	System	04 Mar 2021 12:48:27
User entered 'No (N)'	System	04 Mar 2021 12:48:27

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

Have you been exposed to someone with 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: '2021-03-04T06:48:17-06:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'b02347d8-56c1-41e2-9e9f-4801c25719e0'	System	04 Mar 2021 12:48:27
User entered 'No (N)'	System	04 Mar 2021 12:48:27

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: '2021-03-04T06:48:20-06:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'b02347d8-56c1-41e2-9e9f-4801c25719e0' User entered '04 Mar 2021 06:48:20'	System	04 Mar 2021 12:48:27
	System	04 Mar 2021 12:48:27

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: '2021-03-11T06:33:01-06:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'cbfdd6b2-aed5-46ef-8313-90f4e2c1490c'	System	11 Mar 2021 12:33:13
User entered 'No (N)'	System	11 Mar 2021 12:33:13

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

Have you been exposed to someone with 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: '2021-03-11T06:33:06-06:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'cbfdd6b2-aed5-46ef-8313-90f4e2c1490c'	System	11 Mar 2021 12:33:13
User entered 'No (N)'	System	11 Mar 2021 12:33:13

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: '2021-03-11T06:33:10-06:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'cbfdd6b2-aed5-46ef-8313-90f4e2c1490c'	System	11 Mar 2021 12:33:13
User entered '11 Mar 2021 06:33:10'	System	11 Mar 2021 12:33:13

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: '2021-03-20T15:20:24-05:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '843049f5-3f9d-452c-8a6f-803936b094cd'	System	20 Mar 2021 20:20:34
User entered 'No (N)'	System	20 Mar 2021 20:20:34

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

Have you been exposed to someone with 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: '2021-03-20T15:20:27-05:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '843049f5-3f9d-452c-8a6f-803936b094cd' User entered 'No (N)'	System	20 Mar 2021 20:20:34

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: '2021-03-20T15:20:29-05:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '843049f5-3f9d-452c-8a6f-803936b094cd' User entered '20 Mar 2021 15:20:29'	System	20 Mar 2021 20:20:34
	System	20 Mar 2021 20:20:34

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: '2021-03-25T12:32:01-05:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'ab5c1ca4-bd6b-4019-9405-ee35963a66ca' User entered 'No (N)'	System	25 Mar 2021 17:32:11
	System	25 Mar 2021 17:32:11

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[Have you been exposed to someone with 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: '2021-03-25T12:32:03-05:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'ab5c1ca4-bd6b-4019-9405-ee35963a66ca' User entered 'No (N)'	System	25 Mar 2021 17:32:11
	System	25 Mar 2021 17:32:11

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: '2021-03-25T12:32:06-05:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'ab5c1ca4-bd6b-4019-9405-ee35963a66ca' User entered '25 Mar 2021 12:32:06'	System	25 Mar 2021 17:32:11
	System	25 Mar 2021 17:32:11

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: '2021-04-03T07:59:12-05:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'abc2d1e0-7fe4-48d7-8ff3-882bf32bc6a1' User entered 'No (N)'	System	03 Apr 2021 12:59:19
	System	03 Apr 2021 12:59:19

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

Have you been exposed to someone with 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: '2021-04-03T07:59:14-05:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'abc2d1e0-7fe4-48d7-8ff3-882bf32bc6a1'	System	03 Apr 2021 12:59:19
User entered 'No (N)'	System	03 Apr 2021 12:59:19

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: '2021-04-03T07:59:17-05:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'abc2d1e0-7fe4-48d7-8ff3-882bf32bc6a1'	System	03 Apr 2021 12:59:19
User entered '03 Apr 2021 07:59:17'	System	03 Apr 2021 12:59:19

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: '2021-04-09T12:06:11-05:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '8d0bb4e8-8af9-4bc5-9383-7154a323a343'	System	09 Apr 2021 17:08:49
User entered 'No (N)'	System	09 Apr 2021 17:08:49

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

Have you been exposed to someone with 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: '2021-04-09T12:06:14-05:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '8d0bb4e8-8af9-4bc5-9383-7154a323a343'	System	09 Apr 2021 17:08:49
User entered 'No (N)'	System	09 Apr 2021 17:08:49

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: '2021-04-09T12:06:18-05:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '8d0bb4e8-8af9-4bc5-9383-7154a323a343'	System	09 Apr 2021 17:08:49
User entered '09 Apr 2021 12:06:18'	System	09 Apr 2021 17:08:49

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: '2021-04-15T06:07:42-05:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'a74c4e83-cbce-468e-8fe9-f3ee6f797166'	System	19 Apr 2021 12:16:18
User entered 'No (N)'	System	19 Apr 2021 12:16:18

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

Have you been exposed to someone with 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: '2021-04-15T06:07:46-05:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'a74c4e83-cbce-468e-8fe9-f3ee6f797166'	System	19 Apr 2021 12:16:18
User entered 'No (N)'	System	19 Apr 2021 12:16:18

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: '2021-04-15T06:07:52-05:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: 'a74c4e83-cbce-468e-8fe9-f3ee6f797166'	System	19 Apr 2021 12:16:18
User entered '15 Apr 2021 06:07:52'	System	19 Apr 2021 12:16:18

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: '2021-04-22T20:03:08-05:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '61438e30-e1f3-4f73-a0c7-b4de4ea3bb70'	System	23 Apr 2021 01:09:17
User entered 'No (N)'	System	23 Apr 2021 01:09:17

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[Have you been exposed to someone with 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: '2021-04-22T20:03:09-05:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '61438e30-e1f3-4f73-a0c7-b4de4ea3bb70'	System	23 Apr 2021 01:09:17
User entered 'No (N)'	System	23 Apr 2021 01:09:17

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: '2021-04-22T20:03:20-05:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '61438e30-e1f3-4f73-a0c7-b4de4ea3bb70'	System	23 Apr 2021 01:09:17
User entered '22 Apr 2021 20:03:20'	System	23 Apr 2021 01:09:17

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: '2021-05-01T12:06:22-05:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '49430486-ce16-45a7-a290-9d5f36c8dd5a' User entered 'No (N)'	System	01 May 2021 17:07:17
	System	01 May 2021 17:07:17

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[Have you been exposed to someone with 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: '2021-05-01T12:06:34-05:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '49430486-ce16-45a7-a290-9d5f36c8dd5a'	System	01 May 2021 17:07:17
User entered 'No (N)'	System	01 May 2021 17:07:17

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: '2021-05-01T12:06:36-05:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '49430486-ce16-45a7-a290-9d5f36c8dd5a' User entered '01 May 2021 12:06:36'	System	01 May 2021 17:07:17
	System	01 May 2021 17:07:17

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:51:22

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:29:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2021-03-01T21:17:28-06:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '2de5b643-21bb-4172-9577-3734ced6a846'	System	02 Mar 2021 03:19:33
User entered 'No (N)'	System	02 Mar 2021 03:19:33

US3002302

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:51:22

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:29:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F28D337C-14B3-4C33-BCED-F46E814AA1D9)', Time: '2021-03-01T21:17:35-06:00', User OID: 'PatientReportedOutcome (US3002302)', ODM File OID: '2de5b643-21bb-4172-9577-3734ced6a846'	System	02 Mar 2021 03:19:33
User entered '01 Mar 2021 21:17:35'	System	02 Mar 2021 03:19:33

US3002302

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	12 Jan 2021 00:42:06

US3002302

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '09 Dec 2020'	Jessica Satorie (b) (4)	12 Jan 2021 00:42:06

US3002302

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Contact Made (CONTACT MADE)'	Jessica Satorie (b) (4)	12 Jan 2021 00:42:06

US3002302

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	Jessica Satorie (b) (4)	12 Jan 2021 00:42:06

US3002302

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	12 Jan 2021 00:42:18

US3002302

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:17
User entered 'I'	System	12 Jan 2021 00:42:18

US3002302

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:37:30
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	12 Jan 2021 00:53:32

US3002302

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:37:30
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '11 Jan 2021'	Jessica Satorie (b) (4)	12 Jan 2021 00:53:32

US3002302

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:37:30
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'Contact Made (CONTACT MADE)'	Jessica Satorie (b) (4)	12 Jan 2021 00:53:32

US3002302

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:37:30
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered empty.	Jessica Satorie (b) (4)	12 Jan 2021 00:53:32

US3002302

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:37:30
User signature succeeded.	Brandon Essink (b) (4)	23 Feb 2021 17:13:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:31:59

US3002302

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:37:30
User entered 'I'	System	22 Feb 2021 18:31:59

US3002302

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:37:30
User signature succeeded.	Brandon Essink (b) (4)	23 Feb 2021 17:13:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 20:23:41

US3002302

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:37:30
User signature succeeded.	Brandon Essink (b) (4)	23 Feb 2021 17:13:43
User entered '12 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 20:23:41

US3002302

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:37:30
User signature succeeded.	Brandon Essink (b) (4)	23 Feb 2021 17:13:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Feb 2021 20:23:41

US3002302

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:37:30
User signature succeeded.	Brandon Essink (b) (4)	23 Feb 2021 17:13:43
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 20:23:41

US3002302

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:37:30
User signature succeeded.	Brandon Essink (b) (4)	23 Feb 2021 17:13:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 20:23:44

US3002302

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:37:30
User entered 'I'	System	22 Feb 2021 20:23:44

US3002302

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:37:30
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 20:31:21

US3002302

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:37:30
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
User entered '12 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 20:31:21

US3002302

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:37:30
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 20:31:21

US3002302

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:51:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:37:30
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 20:31:21

US3002302

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:37:30
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 20:31:23

US3002302

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:37:30
User entered 'I'	System	22 Mar 2021 20:31:23

US3002302

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:51:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	14 Apr 2021 19:58:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:34:30

US3002302

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	14 Apr 2021 19:58:41
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:34:30

US3002302

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	14 Apr 2021 19:58:41
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:34:30

US3002302

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:51:22

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	12 Apr 2021 19:34:30

US3002302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	14 Apr 2021 19:58:41
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:34:39

US3002302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	14 Apr 2021 19:58:41
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:34:39

US3002302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	14 Apr 2021 19:58:41
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:34:39

US3002302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 19:34:39

US3002302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	14 Apr 2021 19:58:41
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:34:39

US3002302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	14 Apr 2021 19:58:41
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:34:39

US3002302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	14 Apr 2021 19:58:41
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:34:39

US3002302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	14 Apr 2021 19:58:41
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:34:39

US3002302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 19:34:39

US3002302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	14 Apr 2021 19:58:41
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:34:39

US3002302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 19:34:39

US3002302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	14 Apr 2021 19:58:41
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:34:39

US3002302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 19:34:39

US3002302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	14 Apr 2021 19:58:41
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:34:39

US3002302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 19:34:39

US3002302

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:51:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	14 Apr 2021 19:58:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:34:54

US3002302

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:51:22

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	14 Apr 2021 19:58:41
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:34:54

US3002302

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:51:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	14 Apr 2021 19:58:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:35:07

US3002302

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:51:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	14 Apr 2021 19:58:41
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:35:07

US3002302

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:51:22

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	14 Apr 2021 19:58:41
User entered '13:23'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:35:07

US3002302

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:51:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Apr 2021 13:23'	System	12 Apr 2021 19:35:07

US3002302

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	14 Apr 2021 19:58:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:35:14

US3002302

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:51:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 19:35:14

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:51:22

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:16
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:20
User entered '09 Oct 2020'	Jessica Satorie (b) (4)	14 Oct 2020 22:51:57

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:51:22

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:16
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:20
User entered '14:31'	Jessica Satorie (b) (4)	14 Oct 2020 22:51:57
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:51:22

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:16
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: 11 Aug 2021 21:51:22

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:16
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:16
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:20
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	14 Oct 2020 22:51:57
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:51:22

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'Day 1 (Day 1)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:51:22

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
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) (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) (b) (4)	04 Nov 2020 18:52:07
User entered '07 Oct 2020' reason for change: Data Entry Error	Jessica Satorie (b) (4) (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) (b) (4)	14 Oct 2020 22:53:16

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:51:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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'	(b) (4)	
	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:51:22

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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'	(b) (4)	
	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:51:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
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: 11 Aug 2021 21:51:22

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	
User entered '36.9' C	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:51:22

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	
User entered 'None (None)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:51:22

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	
User entered 'Mild (Mild)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:51:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	
User entered 'None (None)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:51:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)'	(b) (4)	
	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:51:22

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	
User entered 'None (None)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:51:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	
User entered 'None (None)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:51:22

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	
User entered 'None (None)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:51:22

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	
User entered 'Moderate (Moderate)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:51:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	
User entered 'None (None)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:51:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)'	(b) (4)	
	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:51:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	
User entered 'Mild (Mild)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:51:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	
User entered 'None (None)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:51:22

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)'	(b) (4)	
	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:51:22

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	
User entered 'None (None)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:51:22

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	
User entered 'None (None)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:51:22

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	
User entered 'None (None)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:16
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:51:22

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'Day 2 (Day 2)'	Jessica Satorie (b) (4)	04 Nov 2020 18:52:21

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:51:22

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '08 Oct 2020'	Jessica Satorie (b) (4)	04 Nov 2020 18:52:21
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:51:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'l'	(b) (4), (b) (6)	04 Nov 2020 18:52:21
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:51:22

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4)	04 Nov 2020 18:52:21
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:51:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User entered empty.	System	04 Nov 2020 18:52:21

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:51:22

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4)	04 Nov 2020 18:52:21
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:51:22

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4)	04 Nov 2020 18:52:21
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:51:22

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4)	04 Nov 2020 18:52:21
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:51:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4)	04 Nov 2020 18:52:21
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:51:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 18:52:21
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:51:22

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4)	04 Nov 2020 18:52:21
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:51:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4)	04 Nov 2020 18:52:21
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:51:22

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4)	04 Nov 2020 18:52:21
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:51:22

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4)	04 Nov 2020 18:52:21
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:51:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4)	04 Nov 2020 18:52:21
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:51:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4)	04 Nov 2020 18:52:21
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:51:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4)	04 Nov 2020 18:52:21
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:51:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4)	04 Nov 2020 18:52:21
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:51:22

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4)	04 Nov 2020 18:52:21
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:51:22

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4)	04 Nov 2020 18:52:21
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:51:22

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4)	04 Nov 2020 18:52:21
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:51:22

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered empty.	Jessica Satorie (b) (4)	04 Nov 2020 18:52:21
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:51:22

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'Day 3 (Day 3)'	Jessica Satorie (b) (4)	04 Nov 2020 18:54:28

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:51:22

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '09 Oct 2020'	Jessica Satorie (b) (4)	04 Nov 2020 18:54:28
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:51:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '0'	Jessica Satorie (b) (4)	04 Nov 2020 18:54:28
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:51:22

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '99'	Jessica Satorie (b) (4)	04 Nov 2020 18:54:28
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:51:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User entered '%'	System	04 Nov 2020 18:54:28

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:51:22

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '36.9' C	Jessica Satorie (b) (4)	04 Nov 2020 18:54:28
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:51:22

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:51:22

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'Mild (Mild)'	Jessica Satorie (b) (4)	04 Nov 2020 18:54:28
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:51:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:51:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 18:54:28
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:51:22

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 18:54:28
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:51:22

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:51:22

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'Moderate (Moderate)'	Jessica Satorie (b) (4)	04 Nov 2020 18:54:28
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:51:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
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: 11 Aug 2021 21:51:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:51:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'Mild (Mild)'	Jessica Satorie (b) (4)	04 Nov 2020 18:54:28
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:51:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 18:54:28
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:51:22

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:51:22

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:51:22

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:51:22

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'Day 4 (Day 4)'	Jessica Satorie (b) (4)	04 Nov 2020 18:55:24

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:51:22

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered '10 Oct 2020'	Jessica Satorie (b) (4)	04 Nov 2020 18:55:24

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:51:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:51:22

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:51:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User entered '%'	System	04 Nov 2020 18:55:24

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:51:22

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '97.6' F	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: 11 Aug 2021 21:51:22

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 18:55:24
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:51:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 17:54:34
	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: 11 Aug 2021 21:51:22

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 18:55:24
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:51:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 17:54:34
	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: 11 Aug 2021 21:51:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 17:54:34
	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: 11 Aug 2021 21:51:22

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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 (5)

Generated On: 11 Aug 2021 21:51:22

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'Day 5 (Day 5)'	Jessica Satorie (b) (4)	04 Nov 2020 18:56:18

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:51:22

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered '11 Oct 2020'	Jessica Satorie (b) (4)	04 Nov 2020 18:56:18

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:51:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '0'	Jessica Satorie (b) (4)	04 Nov 2020 18:56:18

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:51:22

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User entered '%'	System	04 Nov 2020 18:56:18

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:51:22

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '98.1' F	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: 11 Aug 2021 21:51:22

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	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: 11 Aug 2021 21:51:22

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 18:56:18
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:51:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 18:56:18
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:51:22

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	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: 11 Aug 2021 21:51:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 18:56:18
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:51:22

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	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: 11 Aug 2021 21:51:22

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	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: 11 Aug 2021 21:51:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'Mild (Mild)'	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: 11 Aug 2021 21:51:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 18:56:18
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:51:22

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	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: 11 Aug 2021 21:51:22

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 18:56:18
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:51:22

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 18:56:18
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:51:22

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'Day 6 (Day 6)'	Jessica Satorie (b) (4)	04 Nov 2020 18:56:44

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:51:22

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered '12 Oct 2020'	Jessica Satorie (b) (4)	04 Nov 2020 18:56:44

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:51:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:51:22

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '99'	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: 11 Aug 2021 21:51:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User entered '%'	System	04 Nov 2020 18:56:44

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:51:22

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '98.2' F	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: 11 Aug 2021 21:51:22

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 17:54:34
	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: 11 Aug 2021 21:51:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 17:54:34
	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: 11 Aug 2021 21:51:22

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 18:56:44
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:51:22

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 18:56:44
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:51:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 18:56:44
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:51:22

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'Day 7 (Day 7)'	Jessica Satorie (b) (4)	04 Nov 2020 18:57:19

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:51:22

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '13 Oct 2020'	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: 11 Aug 2021 21:51:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered '0'	Jessica Satorie (b) (4)	04 Nov 2020 18:57:19

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:51:22

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '98'	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: 11 Aug 2021 21:51:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User entered '%'	System	04 Nov 2020 18:57:19

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:51:22

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered '97.1' F	Jessica Satorie (b) (4)	04 Nov 2020 18:57:19

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:51:22

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 18:57:19
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:51:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 18:57:19
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:51:22

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 18:57:19
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:51:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 18:57:19
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:51:22

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'Day 8 (Day 8)'	Jessica Satorie (b) (4)	04 Nov 2020 18:58:01

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:51:22

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered '14 Oct 2020'	Jessica Satorie (b) (4)	04 Nov 2020 18:58:01

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:51:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered '0'	Jessica Satorie (b) (4)	04 Nov 2020 18:58:01

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:51:22

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '99'	Jessica Satorie (b) (4)	04 Nov 2020 18:58:01
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:51:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User entered '%'	System	04 Nov 2020 18:58:01

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:51:22

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '97.8' F	Jessica Satorie (b) (4)	04 Nov 2020 18:58:01
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:51:22

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:58:01
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:51:22

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'Mild (Mild)'	Jessica Satorie (b) (4)	04 Nov 2020 18:58:01
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:51:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 18:58:01
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:51:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:58:01
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:51:22

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 18:58:01
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:51:22

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:58:01
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:51:22

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 18:58:01
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:51:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:58:01
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:51:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:58:01
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:51:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 18:58:01
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:51:22

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:58:01
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:51:22

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:58:01
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:51:22

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 18:58:01
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:51:22

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 18:58:01
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:51:22

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'Day 9 (Day 9)'	Jessica Satorie (b) (4)	04 Nov 2020 18:58:40

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:51:22

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered '15 Oct 2020'	Jessica Satorie (b) (4)	04 Nov 2020 18:58:40

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:51:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 18:58:40
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:51:22

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '99'	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: 11 Aug 2021 21:51:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User entered '%'	System	04 Nov 2020 18:58:40

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:51:22

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '97.8' F	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: 11 Aug 2021 21:51:22

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 18:58:40
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:51:22

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 17:54:34
	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: 11 Aug 2021 21:51:22

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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 (10)

Generated On: 11 Aug 2021 21:51:22

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'Day 10 (Day 10)'	Jessica Satorie (b) (4)	04 Nov 2020 18:59:36

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:51:22

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered '16 Oct 2020'	Jessica Satorie (b) (4)	04 Nov 2020 18:59:36

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:51:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '0'	Jessica Satorie (b) (4)	04 Nov 2020 18:59:36

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:51:22

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '99'	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: 11 Aug 2021 21:51:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User entered '%'	System	04 Nov 2020 18:59:36

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:51:22

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '97.3' F	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: 11 Aug 2021 21:51:22

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'Mild (Mild)'	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: 11 Aug 2021 21:51:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 18:59:36
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:51:22

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 18:59:36
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:51:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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 (11)

Generated On: 11 Aug 2021 21:51:22

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'Day 11 (Day 11)'	Jessica Satorie (b) (4)	04 Nov 2020 19:00:05

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:51:22

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '17 Oct 2020'	Jessica Satorie (b) (4)	04 Nov 2020 19:00:05
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:51:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '0'	Jessica Satorie (b) (4)	04 Nov 2020 19:00:05
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:51:22

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '99'	Jessica Satorie (b) (4)	04 Nov 2020 19:00:05
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:51:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User entered '%'	System	04 Nov 2020 19:00:05

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:51:22

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '97.1' F	Jessica Satorie (b) (4)	04 Nov 2020 19:00:05
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:51:22

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:51:22

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:51:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:00:05
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:51:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:00:05
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:51:22

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:00:05
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:51:22

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:51:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:51:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:00:05
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:51:22

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:51:22

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:51:22

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:51:22

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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 (12)

Generated On: 11 Aug 2021 21:51:22

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'Day 12 (Day 12)'	Jessica Satorie (b) (4)	04 Nov 2020 19:00:37

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:51:22

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered '18 Oct 2020'	Jessica Satorie (b) (4)	04 Nov 2020 19:00:37

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:51:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 19:00:37
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:51:22

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:51:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User entered '%'	System	04 Nov 2020 19:00:37

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:51:22

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '99.0' F	Jessica Satorie (b) (4)	04 Nov 2020 19:00:37
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:51:22

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:51:22

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:51:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:51:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:51:22

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:00:37
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:51:22

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:51:22

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:00:37
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:51:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
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: 11 Aug 2021 21:51:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:51:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:00:37
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:51:22

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:51:22

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:51:22

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:51:22

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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 (13)

Generated On: 11 Aug 2021 21:51:22

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'Day 13 (Day 13)'	Jessica Satorie (b) (4)	04 Nov 2020 19:03:43

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:51:22

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '19 Oct 2020'	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: 11 Aug 2021 21:51:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
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

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:51:22

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '99'	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: 11 Aug 2021 21:51:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User entered '%'	System	04 Nov 2020 19:03:43

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:51:22

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '98.8' F	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: 11 Aug 2021 21:51:22

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 17:54:34
	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: 11 Aug 2021 21:51:22

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
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: 11 Aug 2021 21:51:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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 (14)

Generated On: 11 Aug 2021 21:51:22

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'Day 14 (Day 14)'	Jessica Satorie (b) (4)	04 Nov 2020 19:04:37

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:51:22

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '20 Oct 2020'	Jessica Satorie (b) (4)	04 Nov 2020 19:04:37
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:51:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
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

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:51:22

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '98'	Jessica Satorie (b) (4)	04 Nov 2020 19:04:37
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:51:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User entered '%'	System	04 Nov 2020 19:04:37

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:51:22

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '97.4' F	Jessica Satorie (b) (4)	04 Nov 2020 19:04:37
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:51:22

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:51:22

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:04:37
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:51:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 17:54:34
	Jessica Satorie (b) (4)	04 Nov 2020 19:04:37
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:51:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:04:37
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:51:22

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:51:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:51:22

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:51:22

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:51:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:04:37

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:51:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:51:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:04:37
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:51:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:51:22

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:51:22

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:51:22

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:51:22

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4)	04 Nov 2020 19:04:37

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:51:22

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'Day 15 (Day 15)'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:13

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:51:22

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered '21 Oct 2020'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:13

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:51:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered '0'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:13

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:51:22

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:51:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User entered '%'	System	04 Nov 2020 19:05:13

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:51:22

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '97.2' F	Jessica Satorie (b) (4)	04 Nov 2020 19:05:13
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:51:22

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:51:22

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:51:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:05:13
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:51:22

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:05:13
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:51:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:51:22

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:05:13
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:51:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:51:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:51:22

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:51:22

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:51:22

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:51:22

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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 (17)

Generated On: 11 Aug 2021 21:51:22

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
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)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:51:22

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered '22 Oct 2020'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:53

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:51:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 19:05:53
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:51:22

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered '98'	Jessica Satorie (b) (4)	04 Nov 2020 19:05:53

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:51:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User entered '%'	System	04 Nov 2020 19:05:53

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:51:22

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '97.9' F	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: 11 Aug 2021 21:51:22

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:05:53
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:51:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 17:54:34
	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: 11 Aug 2021 21:51:22

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:05:53
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:51:22

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: 11 Aug 2021 21:51:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:05:53
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:51:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	05 Nov 2020 17:54:34
User entered 'None (None)'	(b) (4), (b) (6)	04 Nov 2020 19:05:53
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:51:22

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:51:22

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:34
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
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) (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) (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) (b) (4)	14 Oct 2020 22:53:51

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:51:22

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:34
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:34
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
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)	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)	14 Oct 2020 22:53:51

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:51:22

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:34
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	27 Oct 2020 19:38:35
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: 11 Aug 2021 21:51:22

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:34
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:34
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:35:57
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:53:51

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:51:22

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:34
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	27 Oct 2020 19:38:30
User entered 'No (N)'	Jessica Satorie (b) (4)	14 Oct 2020 22:53:51

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:51:22

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:34
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:35:57
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:53:51

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:51:22

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:34
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:35:57
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:53:51

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:51:22

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:34
User entered 'I'	System	14 Oct 2020 22:53:51

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:55:07
User entered 'No (N)'	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33
	(b) (4)	

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:11:25
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'No (N)'	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'No (N)'	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'No (N)'	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'No (N)'	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'No (N)'	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 21:51:22

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'No (N)'	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'No (N)'	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'No (N)'	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'No (N)'	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

Evidence of Shock Requires
Vasopressors

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 21:51:22

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 21:51:22

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 21:51:22

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'No (N)'	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'No (N)'	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'No (N)'	(b) (4) 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: 11 Aug 2021 21:51:22

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'No (N)'	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:51:22

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:41
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:36:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 21:51:22

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:14:48
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:33:47
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:27:11
DataPoint Un-verified.	(b) (4) Jessica Satorie (b) (4)	26 Feb 2021 17:30:21
Signature has been broken.	(b) (4) Jessica Satorie (b) (4)	26 Feb 2021 17:30:21
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Jessica Satorie (b) (4)	26 Feb 2021 17:30:21
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:27:42
User entered 'No (N)'	(b) (4) Jessica Satorie (b) (4)	14 Oct 2020 22:55:38

US3002302

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:51:22

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:29
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: 11 Aug 2021 21:51:22

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:29
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:27:11
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:29
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:27:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:56:52
User entered '11 Oct 2020'	Jessica Satorie (b) (4)	04 Nov 2020 17:33:23
	(b) (4)	

US3002302

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:51:22

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:29
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: 11 Aug 2021 21:51:22

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:29
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:27:11
DataPoint Verified.	(b) (4)	05 Nov 2020 17:56:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 17:56:52
	Jessica Satorie (b) (4)	04 Nov 2020 17:33:23
	(b) (4)	

US3002302

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:51:22

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:29
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:27:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:56:52
User entered '13 Oct 2020'	Jessica Satorie (b) (4)	04 Nov 2020 17:33:23
	(b) (4)	

US3002302

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:51:22

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:29
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: 11 Aug 2021 21:51:22

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:29
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:27:11
DataPoint Verified.	(b) (4)	05 Nov 2020 17:56:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 17:56:52
	Jessica Satorie (b) (4)	04 Nov 2020 17:33:23
	(b) (4)	

US3002302

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:51:22

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:29
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:27:11
DataPoint Verified.	(b) (4)	05 Nov 2020 17:56:52
User entered '15 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 17:56:52
	Jessica Satorie (b) (4)	04 Nov 2020 17:33:23
	(b) (4)	

US3002302

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:51:22

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:29
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: 11 Aug 2021 21:51:22

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:29
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:27:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:56:52
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	04 Nov 2020 17:33:23
	(b) (4)	

US3002302

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:51:22

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:29
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:27:11
DataPoint Verified.	(b) (4)	05 Nov 2020 17:56:52
User entered '17 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 17:56:52
	Jessica Satorie (b) (4)	04 Nov 2020 17:33:23
	(b) (4)	

US3002302

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:51:22

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:29
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: 11 Aug 2021 21:51:22

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:29
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:27:11
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:29
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:27:11
DataPoint Verified.	(b) (4)	05 Nov 2020 17:56:52
User entered '22 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 17:56:52
	Jessica Satorie (b) (4)	04 Nov 2020 17:33:23
	(b) (4)	

US3002302

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:51:22

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:29
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: 11 Aug 2021 21:51:22

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:29
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:27:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:31:09
User closed query 'Per GCL Lab Reconciliation Re-query: Saliva: Previous query response states 'data updated', however Sample dated 29OCT2020 is still not updated n EDC. Please consider reviewing and confirm if sample dated 29OCT2020 is collected. If yes, please update the data in EDC. Else clarify. Thank ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 11:17:05
Query 'Per GCL Lab Reconciliation Re-query: Saliva: Previous query response states 'data updated', however Sample dated 29OCT2020 is still not updated n EDC. Please consider reviewing and confirm if sample dated 29OCT2020 is collected. If yes, please update the data in EDC. Else clarify. Thank ' answered with 'corrected' (Site from DM).	Kimberly Mueller (b) (4) (b) (4)	05 Jan 2021 00:13:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Kimberly Mueller (b) (4) (b) (4)	05 Jan 2021 00:13:02
User closed 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)	08 Dec 2020 01:11:07
User opened query 'Per GCL Lab Reconciliation Re-query: Saliva: Previous query response states 'data updated', however Sample dated 29OCT2020 is still not updated n EDC. Please consider reviewing and confirm if sample dated 29OCT2020 is collected. If yes, please update the data in EDC. Else clarify. Thank ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 01:11:06

US3002302

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:51:22

Was Saliva Collected?

Audit	User	Time (GMT)
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.' answered with 'data updated. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 18:44:01
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 18:43:55
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 18:43:55
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: 11 Aug 2021 21:51:22

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:29
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:27:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:31:09
User closed query 'Per GCL LAB reconciliation: Saliva: Day 21 sample dated 27OCT2020 is reported in PPD central lab with 29OCT2020. Please confirm the correct date in response and amend EDC or PPD portal as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 07:14:26
Query 'Per GCL LAB reconciliation: Saliva: Day 21 sample dated 27OCT2020 is reported in PPD central lab with 29OCT2020. Please confirm the correct date in response and amend EDC or PPD portal as appropriate. Thank you.' answered with 'fixed' (Site from DM).	Kimberly Mueller (b) (4) (b) (4)	05 Jan 2021 16:58:29
User entered '29 Oct 2020' reason for change: Data Entry Error	Kimberly Mueller (b) (4) (b) (4)	05 Jan 2021 16:58:16
User opened query 'Per GCL LAB reconciliation: Saliva: Day 21 sample dated 27OCT2020 is reported in PPD central lab with 29OCT2020. Please confirm the correct date in response and amend EDC or PPD portal as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 11:18:04
DataPoint Un-verified.	Kimberly Mueller (b) (4) (b) (4)	05 Jan 2021 00:13:42
User entered '27 Oct 2020' reason for change: Data Entry Error	Kimberly Mueller (b) (4) (b) (4)	05 Jan 2021 00:13:42
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: 11 Aug 2021 21:51:22

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:29
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: 11 Aug 2021 21:51:22

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:29
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:11:56
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:27:11
DataPoint Un-verified.	Jessica Satorie (b) (4)	26 Feb 2021 17:32:19
User entered 'No (N)' reason for change: Data Entry Error	Jessica Satorie (b) (4)	26 Feb 2021 17:32:19
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:31:09
DataPoint Un-verified.	Kimberly Mueller (b) (4)	05 Jan 2021 00:13:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Kimberly Mueller (b) (4)	05 Jan 2021 00:13:42
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:56:52
User entered 'No (N)'	Jessica Satorie (b) (4)	04 Nov 2020 17:33:23

US3002302

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:51:22

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:29
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:11:56
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:27:11
User closed query 'Per GCL LAB reconciliation: Saliva: DAY 28 visit sample dated 03NOV2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 03:47:49
Query 'Per GCL LAB reconciliation: Saliva: DAY 28 visit sample dated 03NOV2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' answered with 'Nasal swab done instead' (Site from DM).	Jessica Satorie (b) (4) (b) (4)	26 Feb 2021 17:32:28
DataPoint Un-verified.	Jessica Satorie (b) (4) (b) (4)	26 Feb 2021 17:32:19
User entered empty; reason for change Data Entry Error	Jessica Satorie (b) (4) (b) (4)	26 Feb 2021 17:32:19
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:31:09
User opened query 'Per GCL LAB reconciliation: Saliva: DAY 28 visit sample dated 03NOV2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 07:14:46
DataPoint Un-verified.	Kimberly Mueller (b) (4) (b) (4)	05 Jan 2021 00:13:42
User entered '03 Nov 2020' reason for change: Data Entry Error	Kimberly Mueller (b) (4) (b) (4)	05 Jan 2021 00:13:42
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: 11 Aug 2021 21:51:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:39
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User closed query 'Per ETRTR: Please complete data entry for Saliva Collection page, thanks.' (Site from CRA).	(b) (4) (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) (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) (b) (4)	14 Oct 2020 22:56:33

US3002302

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:39
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:39
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:39
User entered 'SICKD1'	System	14 Oct 2020 22:56:33

US3002302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:43
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:55:58
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	14 Oct 2020 22:57:29
	(b) (4)	

US3002302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:43
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:43
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:55:58
User entered '15:29'	Jessica Satorie (b) (4)	14 Oct 2020 22:57:29
	(b) (4)	

US3002302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:43
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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:43
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:55:58
User entered '36.9' C	Jessica Satorie (b) (4)	14 Oct 2020 22:57:29
	(b) (4)	

US3002302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:43
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:43
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:43
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:43
User entered 'bpm'	System	14 Oct 2020 22:57:29

US3002302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:43
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:55:58
User entered '16'	Jessica Satorie (b) (4)	14 Oct 2020 22:57:29
	(b) (4)	

US3002302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:43
User entered 'breaths/min'	System	14 Oct 2020 22:57:29

US3002302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:43
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:43
User entered 'mmHg'	System	14 Oct 2020 22:57:29

US3002302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:43
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
Signature has been broken indirectly.	(b) (4)	24 Mar 2021 22:30:36
User signature succeeded.	System	24 Mar 2021 22:30:36
	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:58
	(b) (4)	
User entered '86'	Jessica Satorie (b) (4)	14 Oct 2020 22:57:29
	(b) (4)	

US3002302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:43
User entered 'mmHg'	System	14 Oct 2020 22:57:29

US3002302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:43

US3002302

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:43

US3002302

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:51:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:47
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:47
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:52
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:52
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:59
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:59
Query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted however, COVID -19 Assessment form not updated in EDC. Please reconcile the data and update. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 05:39:23
User opened query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted however, COVID -19 Assessment form not updated in EDC. Please reconcile the data and update. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 05:47:52
User closed query 'Per GCL Lab Reconciliation: Swab: Re-query: Since Convalescence Visit does not have form for recording the swab so any Swab collected in that visit will be recorded on COVID Diagnostic form under COVID-19 Assessment visit. Please initiate a COVID -19 Assessment visit dated 05NOV2020 and update on the corresponding COVID Diagnostic form and please contact monitor for more details. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 05:47:52
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
Query 'Per GCL Lab Reconciliation: Swab: Re-query: Since Convalescence Visit does not have form for recording the swab so any Swab collected in that visit will be recorded on COVID Diagnostic form under COVID-19 Assessment visit. Please initiate a COVID -19 Assessment visit dated 05NOV2020 and update on the corresponding COVID Diagnostic form and please contact monitor for more details. Thank you.' answered with 'done' (Site from DM).	Kimberly Mueller (b) (4)	24 Mar 2021 22:27:52
User opened query 'Per GCL Lab Reconciliation: Swab: Re-query: Since Convalescence Visit does not have form for recording the swab so any Swab collected in that visit will be recorded on COVID Diagnostic form under COVID-19 Assessment visit. Please initiate a COVID -19 Assessment visit dated 05NOV2020 and update on the corresponding COVID Diagnostic form and please contact monitor for more details. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 06:29:14

US3002302

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:51:22

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 05NOV2020 under Convalescence Visit Day 28 in PPD central lab for the subject US3002302, however same is missing in EDC. additional swab can be recorded under COVID-19 Assessment visit- COVID diagnostic form. Please review and initiate a COVID-19 Assessment visit and record the swab under COVID Diagnostic form. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 06:29:14
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 05NOV2020 under Convalescence Visit Day 28 in PPD central lab for the subject US3002302, however same is missing in EDC. additional swab can be recorded under COVID-19 Assessment visit- COVID diagnostic form. Please review and initiate a COVID-19 Assessment visit and record the swab under COVID Diagnostic form. Thank you.' answered with 'Next covid assessment form did not appear for me to enter ' (Site from DM).	Jessica Satorie (b) (4) (b) (4)	26 Feb 2021 17:33:29
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 05NOV2020 under Convalescence Visit Day 28 in PPD central lab for the subject US3002302, however same is missing in EDC. additional swab can be recorded under COVID-19 Assessment visit- COVID diagnostic form. Please review and initiate a COVID-19 Assessment visit and record the swab under COVID Diagnostic form. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 11:43:05
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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:59
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:31:48
User entered 'Clinic (Clinic)'	Jessica Satorie (b) (4)	05 Nov 2020 22:18:47
	(b) (4)	

US3002302

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:51:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:59
User entered 'SICKD28'	System	05 Nov 2020 22:18:47

US3002302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:03
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User closed 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) (4), (b) (6)	25 Nov 2020 07:58:57
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: 11 Aug 2021 21:51:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:03
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:03
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:32:26
User entered '08:28'	Jessica Satorie (b) (4)	05 Nov 2020 22:20:27
	(b) (4)	

US3002302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:03
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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:03
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:03
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:03
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:32:26
User entered '36.8' C	Jessica Satorie (b) (4)	05 Nov 2020 22:20:27
	(b) (4)	

US3002302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:03
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:32:26
User entered 'Oral (Oral)'	Jessica Satorie (b) (4)	05 Nov 2020 22:20:27
	(b) (4)	

US3002302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:03
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:03
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:03
User entered 'bpm'	System	05 Nov 2020 22:20:27

US3002302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:03
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:32:26
User entered '12'	Jessica Satorie (b) (4)	05 Nov 2020 22:20:27
	(b) (4)	

US3002302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:03
User entered 'breaths/min'	System	05 Nov 2020 22:20:27

US3002302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:03
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:03
User entered 'mmHg'	System	05 Nov 2020 22:20:27

US3002302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:03
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:32:26
User entered '90'	Jessica Satorie (b) (4)	05 Nov 2020 22:20:27
	(b) (4)	

US3002302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:03
User entered 'mmHg'	System	05 Nov 2020 22:20:27

US3002302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:03

US3002302

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:51:22

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:03

US3002302

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:51:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:07
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:32:35
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	05 Nov 2020 22:20:41
	(b) (4)	

US3002302

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:51:22

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:07
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:32:35
User entered '05 Nov 2020'	Jessica Satorie (b) (4)	05 Nov 2020 22:20:41
	(b) (4)	

US3002302

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 21:51:22

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:24
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:23:24
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:51:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:26
User signature succeeded.	Brandon Essink (b) (4)	23 Feb 2021 17:13:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 17:59:07

US3002302

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

Form: Visit Date

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:26
User signature succeeded.	Brandon Essink (b) (4)	23 Feb 2021 17:13:43
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:59:07

US3002302

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

Form: Visit Date

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:26
User signature succeeded.	Brandon Essink (b) (4)	23 Feb 2021 17:13:43
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Feb 2021 17:59:07

US3002302

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

Form: Visit Date

Generated On: 11 Aug 2021 21:51:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:26
User entered 'UNBLND_DECIDE'	System	22 Feb 2021 17:59:07

US3002302

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

Form: Unblinding

Generated On: 11 Aug 2021 21:51:22

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:26
User signature succeeded.	Brandon Essink (b) (4)	23 Feb 2021 17:13:43
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:59:39

US3002302

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

Form: Unblinding

Generated On: 11 Aug 2021 21:51:22

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:26
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:53:14
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:06:21

US3002302

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

Form: Unblinding

Generated On: 11 Aug 2021 21:51:22

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:26
User signature succeeded.	Brandon Essink (b) (4)	23 Feb 2021 17:13:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:59:39

US3002302

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

Form: Unblinding

Generated On: 11 Aug 2021 21:51:22

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:26
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:53:14
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:06:21

US3002302

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

Form: Unblinding

Generated On: 11 Aug 2021 21:51:22

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:26
User signature succeeded.	Brandon Essink (b) (4)	23 Feb 2021 17:13:43
User entered '22 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 17:59:39

US3002302

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

Form: Unblinding

Generated On: 11 Aug 2021 21:51:22

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:26
User signature succeeded.	Brandon Essink (b) (4)	23 Feb 2021 17:13:43
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	22 Feb 2021 17:59:39

US3002302

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

Form: Unblinding

Generated On: 11 Aug 2021 21:51:22

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:26
User signature succeeded.	Brandon Essink (b) (4)	23 Feb 2021 17:13:43
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:59:39

US3002302

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

Form: Unblinding

Generated On: 11 Aug 2021 21:51:22

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:26
User signature succeeded.	Brandon Essink (b) (4)	23 Feb 2021 17:13:43
User entered 'Not Administered (NA)'	(b) (4), (b) (6)	22 Feb 2021 17:59:39

US3002302

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

Form: Unblinding

Generated On: 11 Aug 2021 21:51:22

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:26
User signature succeeded.	Brandon Essink (b) (4)	23 Feb 2021 17:13:43
User entered 'No (N)'	(b) (4), (b) (6)	22 Feb 2021 17:59:39

US3002302

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

Form: Unblinding

Generated On: 11 Aug 2021 21:51:22

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:26
User entered '1'	System	22 Feb 2021 17:59:39

US3002302

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

Form: Unblinding

Generated On: 11 Aug 2021 21:51:22

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:26
User entered empty.	System	22 Feb 2021 17:59:39

US3002302

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:51:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:26
User signature succeeded.	Brandon Essink (b) (4)	23 Feb 2021 17:13:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 17:59:49

US3002302

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:51:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:26
User signature succeeded.	Brandon Essink (b) (4)	23 Feb 2021 17:13:43
User entered '22 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 17:59:49

US3002302

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:51:22

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:26
User signature succeeded.	Brandon Essink (b) (4)	23 Feb 2021 17:13:43
User entered '08:20'	(b) (4), (b) (6)	22 Feb 2021 17:59:49

US3002302

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:51:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:26
User entered '22 Feb 2021 08:20'	System	22 Feb 2021 17:59:49

US3002302

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:51:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:26
User signature succeeded.	Brandon Essink (b) (4)	23 Feb 2021 17:13:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 18:00:00

US3002302

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:51:22

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:26
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 22FEB2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 05:42:49
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 22FEB2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' answered with 'accession # 1F60J3O' (Site from DM).	Kimberly Mueller (b) (4)	24 Mar 2021 22:27:23
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 22FEB2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 09:12:09
User signature succeeded.	Brandon Essink (b) (4)	23 Feb 2021 17:13:43
User entered '22 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 18:00:00

US3002302

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:51:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:26
User signature succeeded.	Brandon Essink (b) (4)	23 Feb 2021 17:13:43
User entered '08:26'	(b) (4), (b) (6)	22 Feb 2021 18:00:00

US3002302

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:51:22

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:26
User entered '22 Feb 2021 08:26'	System	22 Feb 2021 18:00:00

US3002302

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 21:51:22

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:58:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:35:13
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
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)	24 Mar 2021 22:09:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 22:09:46
Data point term sent to Coder	System	24 Mar 2021 22:08:38
DataPoint Un-verified.	Kimberly Mueller (b) (4)	24 Mar 2021 22:08:29
Coding entries removed.	(b) (4)	24 Mar 2021 22:08:29
Signature has been broken.	Kimberly Mueller (b) (4)	24 Mar 2021 22:08:29
User entered 'TOOTH ABsCESS' reason for change: Data Entry Error	(b) (4)	24 Mar 2021 22:08:29
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	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.	(b) (4), (b) (6)	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	(b) (4)	14 Oct 2020 22:59:53
User entered 'Tooth Abcess'	System	14 Oct 2020 22:59:43
	Jessica Satorie (b) (4)	
	(b) (4)	

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:35:13
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Un-verified.	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:08:29
Signature has been broken.	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:08:29
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:08:29
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered 'No (N)'	(b) (4) Jessica Satorie (b) (4)	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered 'No (N)'	Jessica Satorie (b) (4)	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered '20 Sep 2020'	Jessica Satorie (b) (4)	14 Oct 2020 22:59:43
	(b) (4)	

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:59:43
	(b) (4)	

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User entered empty.	System	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
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: 11 Aug 2021 21:51:22

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User entered empty.	System	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessica Satorie (b) (4)	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered 'No (N)'	Jessica Satorie (b) (4)	14 Oct 2020 22:59:43
	(b) (4)	

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered '0'	Jessica Satorie (b) (4)	14 Oct 2020 22:59:43
	(b) (4)	

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	06 Nov 2020 15:33:40
User entered '0'	Jessica Satorie (b) (4)	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered '0'	Jessica Satorie (b) (4)	14 Oct 2020 22:59:43
	(b) (4)	

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered '0'	Jessica Satorie (b) (4)	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered '0'	Jessica Satorie (b) (4)	14 Oct 2020 22:59:43
	(b) (4)	

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	
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
	(b) (4)	

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User signature succeeded.	Brandon Essink (b) (4)	01 May 2021 11:49:03
User closed query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Apr 2021 09:19:58
Query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate, else clarify. ' answered with 'updated' (Site from DM).	Jessica Satorie (b) (4) (b) (4)	22 Apr 2021 21:08:21
DataPoint Un-verified.	Jessica Satorie (b) (4) (b) (4)	22 Apr 2021 21:07:31
Signature has been broken.	Jessica Satorie (b) (4) (b) (4)	22 Apr 2021 21:07:31
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jessica Satorie (b) (4) (b) (4)	22 Apr 2021 21:07:31
User opened query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 13:17:39
User signature succeeded.	Brandon Essink (b) (4) (b) (4)	15 Feb 2021 12:48:41
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) (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) (b) (4)	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
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) (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: 11 Aug 2021 21:51:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered '0'	Jessica Satorie (b) (4)	14 Oct 2020 22:59:43
	(b) (4)	

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Un-verified.	Jessica Satorie (b) (4)	19 Nov 2020 22:45:22
User entered '1' reason for change: Data Entry Error	Jessica Satorie (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)	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:59:43
	(b) (4)	

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4)	14 Oct 2020 22:59:43
	(b) (4)	

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User entered '0'	System	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08
User entered '1'	System	24 Mar 2021 22:08:29
User entered '0'	System	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:51:22

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:50:08

US3002302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:51:22

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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	System	15 Oct 2020 12:32:26
'USA-US005-2020-mRNA-1273-P301000005'		
User entered 'New'	(b) (4), (b) (6)	15 Oct 2020 12:32:26

US3002302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:51:22

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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)	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)	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)	14 Oct 2020 23:05:12
	(b) (4)	

US3002302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:51:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	14 Oct 2020 23:05:12

US3002302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:51:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	14 Oct 2020 23:05:12

US3002302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:51:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
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) (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) (b) (4)	19 Nov 2020 22:22:59
DataPoint Un-verified.	Jessica Satorie (b) (4) (b) (4)	19 Nov 2020 22:22:51
User entered '17 Oct 2020' reason for change: Data Entry Error	Jessica Satorie (b) (4) (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) (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) (b) (4)	04 Nov 2020 17:35:41

US3002302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:51:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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
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: 11 Aug 2021 21:51:22

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	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) (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) (b) (4)	04 Nov 2020 18:22:42

US3002302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:51:22

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: 11 Aug 2021 21:51:22

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(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:	Jessica Satorie (b) (4)	04 Nov 2020 18:16:34
Data Entry Error	(b) (4)	
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
	(b) (4)	

US3002302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:51:22

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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

US3002302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:51:22

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Patient stated sinus cold/ pressure, coughing, sore throat and drainage starting' reason for change: Data Entry Error	Jessica Satorie (b) (4)	04 Nov 2020 18:28:01
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)	14 Oct 2020 23:05:12

US3002302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[Medically Attended AE 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 (3)

Generated On: 11 Aug 2021 21:51:22

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Reproductive tract and breast procedural complications, PT: Uterine perforation, LLT: Uterine perforation post procedural - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 10:11:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 10:11:29
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:35:13
User signature succeeded.	Brandon Essink (b) (4) (b) (4)	25 Mar 2021 12:46:06
Data point term sent to Coder	System	24 Mar 2021 22:08:38
DataPoint Un-verified.	Kimberly Mueller (b) (4) (b) (4)	24 Mar 2021 22:08:05
Coding entries removed.	Kimberly Mueller (b) (4) (b) (4)	24 Mar 2021 22:08:05
User entered 'IUD perforation of uterine wall' reason for change: Data Entry Error	Kimberly Mueller (b) (4) (b) (4)	24 Mar 2021 22:08:05
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User coded data point as SOC: Product issues, HLGT: Device issues, HLT: Device issues NEC, PT: Device dislocation, LLT: IUD dislocation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 21:52:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 21:52:46
Data point term sent to Coder	System	26 Feb 2021 20:49:07
Coding entries removed.	(b) (4), (b) (6)	26 Feb 2021 20:48:32
User entered 'MALPOSITIONED IUD' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 20:48:32
User coded data point as SOC: Product issues, HLGT: Device issues, HLT: Device issues NEC, PT: Device dislocation, LLT: IUD migration - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 23:31:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 23:31:03
Data point term sent to Coder	System	22 Feb 2021 20:25:28
User entered 'Dislodged IUD'	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User entered 'No (N)'	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User entered 'No (N)'	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:35:13
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Un-verified.	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:08:05
User entered '01 Feb 2021' reason for change: Data Entry Error	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:08:05
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User entered '05 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User entered empty.	System	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:35:13
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Un-verified.	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 21:13:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 21:13:59
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:35:13
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Un-verified.	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 21:13:59
User entered '12 Mar 2021' reason for change: Data Entry Error	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 21:13:59
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User entered empty.	System	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Verified.	(b) (4)	22 Mar 2021 15:12:48
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 20:48:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Feb 2021 20:48:38
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	System	26 Feb 2021 20:48:38
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	22 Feb 2021 20:24:38
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User entered 'No (N)'	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 08:07:40
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'added' (Site from DM).	Kimberly Mueller (b) (4)	24 Mar 2021 21:13:29
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	28 Feb 2021 01:39:05
User entered 'I'	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:35:13
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Un-verified.	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 21:13:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 21:13:59
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:12:48
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User entered '0'	System	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08
User entered 'I'	System	22 Feb 2021 20:24:38

US3002302

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:51:22

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:52:08

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:58:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User closed query 'Per ETRTR: Please confirm and update accordingly whether Medication was dosed for AE COVID-19, thanks.' (Site from CRA).	(b) (4)	
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).	(b) (4), (b) (6)	11 Nov 2020 01:23:17
DataPoint Verified.	Jessica Satorie (b) (4)	09 Nov 2020 23:38:29
	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
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.	(b) (4) Coder Import (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	System	15 Sep 2020 17:06:25
User entered 'Nexium'	(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: 11 Aug 2021 21:51:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'No (N)'	(b) (4) (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: 11 Aug 2021 21:51:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'Gastroesophageal reflux disease'	(b) (4) (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: 11 Aug 2021 21:51:22

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered '20'	(b) (4) (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: 11 Aug 2021 21:51:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'mg (mg)'	(b) (4) (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: 11 Aug 2021 21:51:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	(b) (4) (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: 11 Aug 2021 21:51:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'once daily (QD)'	(b) (4) (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: 11 Aug 2021 21:51:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	(b) (4) (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: 11 Aug 2021 21:51:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'Oral (ORAL)'	(b) (4) (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: 11 Aug 2021 21:51:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	(b) (4) (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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'un UNK 2019'	(b) (4) (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: 11 Aug 2021 21:51:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered '0'	(b) (4) (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: 11 Aug 2021 21:51:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'Yes (Y)'	(b) (4) (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: 11 Aug 2021 21:51:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	(b) (4) (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: 11 Aug 2021 21:51:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'No (N)'	(b) (4) (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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
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.	(b) (4) Coder Import (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)	15 Sep 2020 17:06:15

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:51:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'No (N)'	(b) (4) (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: 11 Aug 2021 21:51:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'Right chronic ankle pain/generalize osteoarthritis'	(b) (4) (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: 11 Aug 2021 21:51:22

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered '200'	(b) (4) (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: 11 Aug 2021 21:51:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'mg (mg)'	(b) (4) (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: 11 Aug 2021 21:51:22

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	(b) (4) (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: 11 Aug 2021 21:51:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'once daily (QD)'	(b) (4) (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: 11 Aug 2021 21:51:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	(b) (4) (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: 11 Aug 2021 21:51:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'Oral (ORAL)'	(b) (4) (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: 11 Aug 2021 21:51:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	(b) (4) (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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'un May 2020'	(b) (4) (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: 11 Aug 2021 21:51:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered '0'	(b) (4) (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: 11 Aug 2021 21:51:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'Yes (Y)'	(b) (4) (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: 11 Aug 2021 21:51:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	(b) (4) (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: 11 Aug 2021 21:51:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'No (N)'	(b) (4) (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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

[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: 11 Aug 2021 21:51:22

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:00:57
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
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 CONGESTION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 17:33:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	18 Dec 2020 17:33:29
User closed query 'Per DM CLR: Please specify the type of SUDAFED PE (eg. Sudafed PE Sinus Congestion, Sudafed PE Sinus Pressure + Pain, etc.) as there are multiple dosage available. Please update medication name as appropriate. Otherwise, please provide clarifications.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 05:13:21
Query 'Per DM CLR: Please specify the type of SUDAFED PE (eg. Sudafed PE Sinus Congestion, Sudafed PE Sinus Pressure + Pain, etc.) as there are multiple dosage available. Please update medication name as appropriate. Otherwise, please provide clarifications.' answered with 'data updated. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 18:37:35
Data point term sent to Coder	System	03 Dec 2020 18:37:35
Coding entries removed.	(b) (4), (b) (6)	03 Dec 2020 18:37:26
User entered 'SUDAFED PE sinus pressure (PHENYLEPHRINE)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 18:37:26
User opened query 'Per DM CLR: Please specify the type of SUDAFED PE (eg. Sudafed PE Sinus Congestion, Sudafed PE Sinus Pressure + Pain, etc.) as there are multiple dosage available. Please update medication name as appropriate. Otherwise, please provide clarifications.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 08:55:03

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:51:22

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) (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) (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) (b) (4)	09 Nov 2020 23:37:13
User entered 'SUDAFED PE (phenylephrine)' reason for change: Data Entry Error	Jessica Satorie (b) (4) (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) (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) (b) (4)	04 Nov 2020 18:25:21

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:51:22

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:00:57
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'No (N)'	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: 11 Aug 2021 21:51:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:00:57
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'COVID-19'	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: 11 Aug 2021 21:51:22

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:00:57
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'I'	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: 11 Aug 2021 21:51:22

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:00:57
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'tablet (TABLET)'	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: 11 Aug 2021 21:51:22

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:00:57
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	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: 11 Aug 2021 21:51:22

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:00:57
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'as needed (PRN)'	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: 11 Aug 2021 21:51:22

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:00:57
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	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: 11 Aug 2021 21:51:22

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:00:57
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'Oral (ORAL)'	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: 11 Aug 2021 21:51:22

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:00:57
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered empty.	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: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:00:57
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
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: 11 Aug 2021 21:51:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:00:57
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered '0'	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: 11 Aug 2021 21:51:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:00:57
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'No (N)'	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: 11 Aug 2021 21:51:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:00:57
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
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: 11 Aug 2021 21:51:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:00:57
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered 'No (N)'	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: 11 Aug 2021 21:51:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:00:57
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: 11 Aug 2021 21:51:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:00:57
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: 11 Aug 2021 21:51:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:00:57
User entered empty.	System	04 Nov 2020 18:25:21

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:51:22

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTOGENS, ATC: PREGNEN (4) DERIVATIVES, PRODUCT: MEDROXYPROGESTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:56:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:56:34
User signature succeeded.	Brandon Essink (b) (4) (b) (4)	25 Mar 2021 12:46:06
Data point term sent to Coder	System	24 Mar 2021 22:12:47
User entered 'medroxyprogesterone'	Kimberly Mueller (b) (4) (b) (4)	24 Mar 2021 22:12:28
DataPoint activated with code reason code Data required.	Kimberly Mueller (b) (4) (b) (4)	24 Mar 2021 22:11:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6) (b) (4)	18 Nov 2020 20:07:26

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:51:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
	(b) (4)	
User entered 'Yes (Y)'	Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 20:07:26

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:51:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
	(b) (4)	
User entered 'endometrial hyperplasia prophylaxis'	Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 20:07:26

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:51:22

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
	(b) (4)	
User entered '10'	Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 20:07:26

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:51:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
	(b) (4)	
User entered 'mg (mg)'	Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 20:07:26

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:51:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 20:07:26

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:51:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
	(b) (4)	
User entered 'other (OTHER)'	Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 20:07:26

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:51:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
	(b) (4)	
User entered 'Day 1-14 of each month'	Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 20:07:26

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:51:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
	(b) (4)	
User entered 'Oral (ORAL)'	Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 20:07:26

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:51:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 20:07:26

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:51:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
	(b) (4)	
User entered '01 Feb 2021'	Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 20:07:26

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:51:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 20:07:26

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:51:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
	(b) (4)	
User entered 'Yes (Y)'	Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 20:07:26

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:51:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 20:07:26

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:51:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
	(b) (4)	
User entered 'No (N)'	Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	18 Nov 2020 20:07:26

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:51:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 22:12:28
DataPoint activated with code reason code Data required.	Kimberly Mueller (b) (4) (b) (4)	24 Mar 2021 22:11:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Nov 2020 20:07:26

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:51:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 22:12:28
DataPoint activated with code reason code Data required.	Kimberly Mueller (b) (4) (b) (4)	24 Mar 2021 22:11:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Nov 2020 20:07:26

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:51:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 22:12:28
DataPoint activated with code reason code Data required.	Kimberly Mueller (b) (4) (b) (4)	24 Mar 2021 22:11:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Nov 2020 20:07:26

US3002302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 21:51:22

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:58:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:34:11
DataPoint Un-verified.	Jessica Satorie (b) (4)	05 Nov 2020 22:17:08
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessica Satorie (b) (4)	05 Nov 2020 22:17:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	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: 11 Aug 2021 21:51:22

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:34:23
User entered '27 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	05 Nov 2020 22:17:37

US3002302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 21:51:22

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
DataPoint Verified.	(b) (4) (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: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Aug 2021 21:51:22

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:56:23
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
User entered '12 Mar 2021'	Kimberly Mueller (b) (4)	24 Mar 2021 21:14:54

US3002302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Aug 2021 21:51:22

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:56:23
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
User entered 'IUD REMOVAL surgery' reason for change: Data Entry Error	(b) (4)	
	Kimberly Mueller (b) (4)	24 Mar 2021 22:08:53
User entered 'IUD removal'	(b) (4)	
	Kimberly Mueller (b) (4)	24 Mar 2021 21:14:54
	(b) (4)	

US3002302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Aug 2021 21:51:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:56:23
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
User entered 'Adverse Event (AE)'	Kimberly Mueller (b) (4)	24 Mar 2021 21:14:54

US3002302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Aug 2021 21:51:22

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:56:23
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:46:06
User entered empty.	Kimberly Mueller (b) (4)	24 Mar 2021 21:14:54

US3002302

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:51:22

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:33:45
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
User entered '13 Oct 2020'	Jessica Satorie (b) (4)	04 Nov 2020 18:21:33

US3002302

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:51:22

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:33:45
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
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) (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) (b) (4)	09 Nov 2020 23:39:00
User entered 'Due to SARS-COV-2 (COVID)' reason for change: Data Entry Error	Jessica Satorie (b) (4) (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) (b) (4)	04 Nov 2020 18:23:31
User entered 'Due to SARS-COV-2 (COVID)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:21:33

US3002302

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:51:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:33:45
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:41
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).	(b) (4) 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: 11 Aug 2021 21:51:22

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

Serious

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
Reviewed for Safety.	(b) (4) (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: 11 Aug 2021 21:51:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '3'	(b) (4)	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: 11 Aug 2021 21:51:22

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

Serious

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
Reviewed for Safety.	(b) (4) (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: 11 Aug 2021 21:51:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '3'	(b) (4)	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: 11 Aug 2021 21:51:22

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
Reviewed for Safety.	(b) (4)	
	(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: 11 Aug 2021 21:51:22

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

Serious

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
Reviewed for Safety.	(b) (4) (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: 11 Aug 2021 21:51:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '3'	(b) (4)	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: 11 Aug 2021 21:51:22

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:24:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '05/Nov/2020 23:29'	(b) (4) System	05 Nov 2020 23:29:49

US3002302

Folder: SAE USA-US005-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 21:51:22

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:24:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
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: 11 Aug 2021 21:51:22

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

Serious

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 21:51:22

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
Reviewed for Safety.	(b) (4) (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: 11 Aug 2021 21:51:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '3'	(b) (4)	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: 11 Aug 2021 21:51:22

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:24:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered '21/Nov/2020 10:52'	(b) (4) System	21 Nov 2020 15:52:04

US3002302

Folder: SAE USA-US005-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 21:51:22

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 23:24:27
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:48:55
User entered 'I'	(b) (4), (b) (6)	21 Nov 2020 15:52:04