

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

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Folder: Screening

Form: Enrollment

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

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Date of Informed Consent (*dd MMM yyyy*) 15 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

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

Generated On: 11 Aug 2021 21:51:22

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

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

Generated On: 11 Aug 2021 21:51:22

Were any significant conditions reported?

Yes

No

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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

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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)	_____

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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)	_____

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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)	_____

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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

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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)	_____

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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.

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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

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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
No

Date of test (dd MMM yyyy) 15 SEP 2020

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

Collection date _____
Collection time _____
Collection date and time (derived) _____

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Folder: Screening

Form: Risk of Exposure

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

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes No

Specify

MERCHANDIZER

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

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

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 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

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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

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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

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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 (<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
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	77 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	89 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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

Generated On: 11 Aug 2021 21:51:22

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	15 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:00 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 10:00
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	86 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 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.

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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 (<i>dd MMM yyyy</i>)	15 SEP 2020
Collection time (<i>00:00-23:59</i>)	08:54 (24 HR)
Collection date and time (derived)	15 SEP 2020 08:54

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

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

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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

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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

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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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

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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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity
- Any use of prescription pain
reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity
- Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp	15 SEP 2020 09:56
PC Open Date & Time	15 SEP 2020 09:47
PC Close Date & Time	15 SEP 2020 12:17

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 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.**

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

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.**

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

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.**

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

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.**

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	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.**

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	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.**

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	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

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

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

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="radio"/>
	Post-Dose <input checked="" 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: 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
No

Visit date (dd MMM yyyy) 05 NOV 2020

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

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
No

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
Axillary
Other

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

Yes

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

No

Yes

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

Date and time of submission 15 NOV 2020 00:02:02

Patient Cloud Open Date & Time 15 NOV 2020 00:01

Patient Cloud Close Date & Time 19 NOV 2020 23:59

US3002302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 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

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 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 <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	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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 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 <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	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 <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 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 <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	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 <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 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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 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 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](#)

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
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](#)

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 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](#)

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

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 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](#)

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
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](#)

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°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](#)

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 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](#)

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
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	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 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](#) 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 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	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°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	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 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](#)

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 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](#)

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 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	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
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](#)

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
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](#)

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 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](#)

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
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 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°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](#)

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
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](#) 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
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	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
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 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

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
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 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 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 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 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](#)

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 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](#)

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 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](#)

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
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](#)

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
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 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 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](#)

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
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](#)

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
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](#)

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 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](#)

30 DEC 2021 00:01

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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 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](#)

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
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](#)

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 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](#)

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 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](#)

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°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](#) 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 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](#)

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°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	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
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](#)

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°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](#)

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 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](#)

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
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](#)

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°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](#)

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°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](#)

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°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	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 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](#)

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 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](#)

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
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](#)

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 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](#)

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°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](#)

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°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	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 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](#)

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
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](#)

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°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](#)

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 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](#)

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 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 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 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	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 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](#)

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 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](#)

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 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](#)

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 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](#)

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 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](#)

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 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](#)

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 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](#) 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 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](#)

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
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](#)

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 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](#) 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 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](#) 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 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](#) 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
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](#)

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 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](#)

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 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](#)

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
No

Visit date (dd MMM yyyy) 12 APR 2021

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

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	12 APR 2021
Collection time (<i>00:00-23:59</i>)	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	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input checked="" type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

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

Generated On: 11 Aug 2021 21:51:22

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

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 _____

O2 Saturation Units _____

Temperature _____

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

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

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

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

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

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 (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	<hr/>
---------------	-------

O2 Saturation Units	<hr/>
---------------------	-------

Temperature	<hr/>
-------------	-------

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"/>

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

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
- 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 (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

302 of 2223

EAB) (1725)

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

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

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

Mild

Moderate

Severe

Not Done

Cough

None

Mild

Moderate

Severe

Not Done

Shortness of Breath

None

Mild

Moderate

Severe

Not Done

Difficulty Breathing

None

Mild

Moderate

Severe

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

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

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

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"/>

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

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

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

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 (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"/>

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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"/>

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EAB) (1725)

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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

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

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"/>

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

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

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

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"/>

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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

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

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

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"/>

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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"/>

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

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

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

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"/>

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

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell 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

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"/>

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

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell 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

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"/>

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

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell 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

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"/>

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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"/>

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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

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

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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
- 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 (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"/>

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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)

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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"/>

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"/>

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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

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell 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

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"/>

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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

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell 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

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
No

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes
No

Date of Test 09 OCT 2020

Type of Test Performed Nasopharyngeal Swab
Nasal Swab
Saliva Test
Other

Other, specify _____

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes
No

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes
No

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 \geq 30 per Minute? Yes
No

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate \geq 125 beats per minute? Yes
No

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of 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 _____

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 _____

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
No

Visit date (dd MMM yyyy) 09 OCT 2020

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

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
No

Date of assessment (dd MMM yyyy) 09 OCT 2020

Time of assessment (00:00-23:59) 15:29 (24 HR)

Vital Signs Date and Time (derived) 09 OCT 2020 15:29

Temperature (xxx.x) 36.9 C

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) 80 beats/min

Pulse units BPM

Respiratory Rate (xxx) 16 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) 140 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) 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
No

Visit date (dd MMM yyyy) 05 NOV 2020

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

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 (<i>dd MMM yyyy</i>)	05 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	08:28 (24 HR)
Vital Signs Date and Time (derived)	05 NOV 2020 08:28
Height (<i>xxx.x</i>)	157.4 cm
Weight (<i>xxx.x</i>)	45 kg
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	77 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3002302

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

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
No

Visit date (dd MMM yyyy) 22 FEB 2021

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

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 (<i>dd MMM yyyy</i>)	22 FEB 2021
Collection time (<i>00:00 - 23:59</i>)	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 <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	20 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	27 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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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
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) 07 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

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
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

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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 <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PATIENT STATED SINUS COLD/ PRESSURE, COUGHING, SORE THROAT AND DRAINAGE. PATIENT DENIED ANY EXPOSURE TO COVID.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
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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)

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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 <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 FEB 2021
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)	12 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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 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

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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="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2019

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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

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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
No

If not Ongoing, End date (dd MMM yyyy) 08 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

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
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

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)
- SAE (specify)
- Death
- Lost To Follow-up
- Physician decision (specify)
- Pregnancy
- Protocol deviation (specify)
- Study Terminated By Sponsor
- Withdrawal of consent by participant (specify)
- Due to SARS-COV-2
- Other

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

US3002302

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 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) (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) (b) (4), (b) (6)	05 Nov 2020 17:58:51
User entered '15 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 13:29:32

US3002302

Folder: Screening

Form: Visit Date

Generated On: 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) (b) (4), (b) (6)	05 Nov 2020 17:58:51
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Sep 2020 16:59:49

US3002302

Folder: Screening

Form: Visit Date

Generated On: 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) (b) (4), (b) (6)	06 Nov 2020 14:51:06
User entered (b) (6) 1970'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 13:29:34

US3002302

Folder: Screening

Form: Demographics

Generated On: 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) (b) (4), (b) (6)	06 Nov 2020 14:51:06
User entered 'Female (F)'	(b) (4), (b) (6)	15 Sep 2020 17:00:00

US3002302

Folder: Screening

Form: Demographics

Generated On: 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) (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) (b) (4), (b) (6)	06 Nov 2020 14:51:06
User entered '1'	(b) (4), (b) (6)	15 Sep 2020 17:00:00

US3002302

Folder: Screening

Form: Demographics

Generated On: 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) (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

[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) (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) (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

[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) (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

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) (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) (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) (b) (4), (b) (6)	06 Nov 2020 14:51:06
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:00:00

US3002302

Folder: Screening

Form: Enrollment

Generated On: 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) (4), (b) (6)	06 Nov 2020 14:51:15
User entered '15 Sep 2020'	Jessica Satorie (b) (4) (b) (4)	15 Sep 2020 14:32:44

US3002302

Folder: Screening

Form: Enrollment

Generated On: 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) (4), (b) (6)	06 Nov 2020 14:51:15
User entered 'Amendment 3 (3)'	Jessica Satorie (b) (4) (b) (4)	15 Sep 2020 14:32:44

US3002302

Folder: Screening

Form: Enrollment

Generated On: 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) (4), (b) (6)	06 Nov 2020 14:51:15
User entered empty.	Jessica Satorie (b) (4) (b) (4)	15 Sep 2020 14:32:44

US3002302

Folder: Screening

Form: Enrollment

Generated On: 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) (b) (4), (b) (6)	06 Nov 2020 14:51:15
User entered empty.	Jessica Satorie (b) (4) (b) (4)	15 Sep 2020 14:32:44

US3002302

Folder: Screening

Form: Enrollment

Generated On: 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) (b) (4)	15 Sep 2020 14:32:44

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) (b) (4), (b) (6)	06 Nov 2020 14:51:15
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 13:29:32

US3002302

Folder: Screening

Form: Enrollment

Generated On: 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 '1'	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)'	(b) (4) Jessica Satorie (b) (4)	15 Sep 2020 14:32:48
	(b) (4)	

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) (6)	04 Nov 2020 11:35:09
User opened query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please note that this is not reflected in the Childbearing Potential eCRF. Please reconcile and update applicable eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 10:58:32
User coded data point as SOC: Surgical and medical procedures, HLG: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 17:01:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 17:01:46
Data point term sent to Coder	System	15 Sep 2020 17:01:11
User entered 'Bilateral tubal ligation'	(b) (4), (b) (6)	15 Sep 2020 17:01:01

US3002302

Folder: Screening

Form: Medical History (1)

Generated On: 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) (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)	

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'	(b) (4) Jessica Satorie (b) (4)	23 Sep 2020 22:53:16
	(b) (4)	

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)'	(b) (4) Jessica Satorie (b) (4)	23 Sep 2020 22:53:16
	(b) (4)	

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.	(b) (4) 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, 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, HLG: 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, HLG: 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'	(b) (4) 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'	(b) (4) 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)'	(b) (4) 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'	(b) (4) 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'	(b) (4) 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) (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) (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) (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) (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) (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) (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) (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) (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) (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) (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) (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) (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) (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) (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) (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) (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) (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) (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) (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) (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) (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) (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) (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) (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) (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) (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) (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 '1'	(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

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) (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) (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) (b) (4), (b) (6)	05 Nov 2020 17:58:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 17:02:26

US3002302

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 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) (b) (4), (b) (6)	05 Nov 2020 17:58:39
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 17:02:26

US3002302

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 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) (b) (4), (b) (6)	05 Nov 2020 17:58:39
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Sep 2020 17:02:26

US3002302

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 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) (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) (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.	(b) (4) Jessica Satorie (b) (4)	15 Sep 2020 14:33:12
	(b) (4)	

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'	(b) (4) Jessica Satorie (b) (4)	15 Sep 2020 14:33:12
	(b) (4)	

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'	(b) (4) 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 '1'	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'	System	15 Sep 2020 14:56:22
User entered 'No (N)'	System	15 Sep 2020 14:56:22

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 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'	System	15 Sep 2020 14:56:22
User entered '15 Sep 2020 09:56'	System	15 Sep 2020 14:56:22

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 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'	System	18 Sep 2020 11:46:36
User entered 'No (N)'	System	18 Sep 2020 11:46:36

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 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'	System	19 Sep 2020 00:52:51
User entered 'Yes (Y)'	System	19 Sep 2020 00:52:51

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 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'	System	19 Sep 2020 00:52:51
User entered '18 Sep 2020 19:52'	System	19 Sep 2020 00:52:51

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 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'	System	19 Sep 2020 23:07:59
User entered 'Yes (Y)'	System	19 Sep 2020 23:07:59

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 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'	System	19 Sep 2020 23:07:59
User entered '19 Sep 2020 18:07'	System	19 Sep 2020 23:07:59

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 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'	System	22 Sep 2020 01:41:30
User entered '97.9'	System	22 Sep 2020 01:41:30

US3002302

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 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' User entered 'None (1)'	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 **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'	System	18 Sep 2020 11:46:53
User entered 'No (N)'	System	18 Sep 2020 11:46:53

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 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'	System	18 Sep 2020 11:46:53
User entered 'No (N)'	System	18 Sep 2020 11:46:53

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 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' 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

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-7163fcd029c' 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-7163fcd029c' 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'	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

[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'	System	19 Sep 2020 23:07:32
User entered 'None (1)'	System	19 Sep 2020 23:07:32

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 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'	System	19 Sep 2020 23:07:32
User entered 'No (N)'	System	19 Sep 2020 23:07:32

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 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'	System	19 Sep 2020 23:07:32
User entered 'No (N)'	System	19 Sep 2020 23:07:32

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 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'	System	19 Sep 2020 23:07:32
User entered 'None (1)'	System	19 Sep 2020 23:07:32

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 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' User entered 'None (1)'	System	20 Sep 2020 22:19:58
	System	20 Sep 2020 22:19:58

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 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' User entered 'None (1)'	System	20 Sep 2020 22:19:58
	System	20 Sep 2020 22:19:58

US3002302

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 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'	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

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'	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

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'	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

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' User entered '15 Sep 2020 09:57'	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

[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'	System	18 Sep 2020 11:47:27
User entered 'None (0)'	System	18 Sep 2020 11:47:27

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 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'	System	18 Sep 2020 11:47:27
User entered 'No (N)'	System	18 Sep 2020 11:47:27

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 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'	System	18 Sep 2020 11:47:27
User entered '18 Sep 2020 06:47'	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'	System	19 Sep 2020 00:51:00
User entered 'None (0)'	System	19 Sep 2020 00:51:00

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 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'	System	19 Sep 2020 00:51:00
User entered 'None (0)'	System	19 Sep 2020 00:51:00

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 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'	System	19 Sep 2020 00:51:00
User entered 'None (0)'	System	19 Sep 2020 00:51:00

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 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'	System	19 Sep 2020 00:51:00
User entered 'None (0)'	System	19 Sep 2020 00:51:00

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 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'	System	19 Sep 2020 00:51:00
User entered 'None (0)'	System	19 Sep 2020 00:51:00

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 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'	System	19 Sep 2020 00:51:00
User entered 'No (N)'	System	19 Sep 2020 00:51:00

US3002302

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 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'	System	19 Sep 2020 23:07:17
User entered 'No (N)'	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)'	(b) (4) Jessica Satorie (b) (4)	23 Sep 2020 22:51:44
	(b) (4)	

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)'	(b) (4) Jessica Satorie (b) (4)	23 Sep 2020 22:51:50
	(b) (4)	

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 '1'	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)'	(b) (4) 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'	(b) (4) Jessica Satorie (b) (4)	04 Nov 2020 21:36:35
	(b) (4)	

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)'	(b) (4) Jessica Satorie (b) (4)	04 Nov 2020 21:36:35
	(b) (4)	

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.	(b) (4) Jessica Satorie (b) (4)	04 Nov 2020 21:36:35
	(b) (4)	

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)'	(b) (4) 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 '1'	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)'	(b) (4) Jessica Satorie (b) (4)	04 Nov 2020 21:37:03
	(b) (4)	

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'	(b) (4) Jessica Satorie (b) (4)	04 Nov 2020 21:37:03
	(b) (4)	

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)'	(b) (4) Jessica Satorie (b) (4)	04 Nov 2020 21:37:03
	(b) (4)	

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.	(b) (4) Jessica Satorie (b) (4)	04 Nov 2020 21:37:03
	(b) (4)	

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)'	(b) (4) Jessica Satorie (b) (4)	04 Nov 2020 21:37:08
	(b) (4)	

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 '1'	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.	(b) (4) 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

[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) (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) (b) (4), (b) (6)	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)'	(b) (4) Jessica Satorie (b) (4)	05 Nov 2020 22:44:01
	(b) (4)	

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 '1'	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)'	(b) (4) Jessica Satorie (b) (4)	05 Nov 2020 22:44:17
	(b) (4)	

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.	(b) (4) Jessica Satorie (b) (4)	05 Nov 2020 22:44:17
	(b) (4)	

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.	(b) (4) Jessica Satorie (b) (4)	05 Nov 2020 22:44:17
	(b) (4)	

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)'	(b) (4) Jessica Satorie (b) (4)	05 Nov 2020 22:44:23
	(b) (4)	

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 '1'	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)'	(b) (4) Jessica Satorie (b) (4)	05 Nov 2020 22:44:29
	(b) (4)	

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.	(b) (4) Jessica Satorie (b) (4)	05 Nov 2020 22:44:29
	(b) (4)	

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.	(b) (4) Jessica Satorie (b) (4)	05 Nov 2020 22:44:29
	(b) (4)	

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.	(b) (4) Jessica Satorie (b) (4)	05 Nov 2020 22:44:29
	(b) (4)	

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)'	(b) (4) Jessica Satorie (b) (4)	05 Nov 2020 22:44:33
	(b) (4)	

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 '1'	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.	(b) (4) 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.	(b) (4) Jessica Satorie (b) (4)	05 Nov 2020 22:44:41
	(b) (4)	

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)'	(b) (4) Jessica Satorie (b) (4)	05 Nov 2020 22:44:45
	(b) (4)	

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 '1'	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'	(b) (4) Jessica Satorie (b) (4)	05 Nov 2020 22:44:56
	(b) (4)	

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)'	(b) (4) Jessica Satorie (b) (4)	05 Nov 2020 22:45:26
	(b) (4)	

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	(b) (4) 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.	(b) (4) Jessica Satorie (b) (4)	05 Nov 2020 22:45:26
	(b) (4)	

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'	(b) (4) Jessica Satorie (b) (4)	05 Nov 2020 22:45:26
	(b) (4)	

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)'	(b) (4) Jessica Satorie (b) (4)	05 Nov 2020 22:45:36
	(b) (4)	

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'	(b) (4) Jessica Satorie (b) (4)	05 Nov 2020 22:45:36
	(b) (4)	

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)'	(b) (4) Jessica Satorie (b) (4)	05 Nov 2020 22:45:52
	(b) (4)	

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)'	(b) (4) Jessica Satorie (b) (4)	05 Nov 2020 22:45:56
	(b) (4)	

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 '1'	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' User entered 'No (N)'	System	15 Nov 2020 06:02:11
	System	15 Nov 2020 06:02:11

US3002302

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 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' User entered 'No (N)'	System	15 Nov 2020 06:02:11
	System	15 Nov 2020 06:02:11

US3002302

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 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'	System	21 Nov 2020 21:31:41
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

Have you been exposed to someone with 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'	System	21 Nov 2020 21:31:41
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'	System	27 Nov 2020 21:13:54
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'	System	27 Nov 2020 21:13:54
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'	System	05 Dec 2020 01:39:57
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'	System	28 Dec 2020 01:47:42
User entered 'No (N)'	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'	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

Have you been exposed to someone with 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'	System	31 Dec 2020 13:04:03
User entered '31 Dec 2020 07:04:00'	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'	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

Have you been exposed to someone with 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' 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

[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'	System	16 Jan 2021 18:00:56
User entered '16 Jan 2021 12:00:38'	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'	System	21 Jan 2021 13:09:19
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
	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
	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'	System	06 Feb 2021 18:02:20
User entered 'No (N)'	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'	System	06 Feb 2021 18:02:20
User entered 'No (N)'	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'	System	11 Feb 2021 17:16:56
User entered '11 Feb 2021 11:10:20'	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'	System	18 Feb 2021 18:51:17
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

Have you been exposed to someone with 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'	System	18 Feb 2021 18:51:17
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'	System	27 Feb 2021 02:50:52
User entered 'No (N)'	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'	System	27 Feb 2021 02:50:52
User entered 'No (N)'	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' 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'	System	25 Mar 2021 17:32:11
User entered 'No (N)'	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'	System	25 Mar 2021 17:32:11
User entered 'No (N)'	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'	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

Have you been exposed to someone with 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)'	(b) (4) Jessica Satorie (b) (4)	12 Jan 2021 00:42:06
	(b) (4)	

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)'	(b) (4) Jessica Satorie (b) (4)	12 Jan 2021 00:42:06
	(b) (4)	

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.	(b) (4) Jessica Satorie (b) (4)	12 Jan 2021 00:42:06
	(b) (4)	

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)'	(b) (4) 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 '1'	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)'	(b) (4) Jessica Satorie (b) (4)	12 Jan 2021 00:53:32
	(b) (4)	

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.	(b) (4) Jessica Satorie (b) (4)	12 Jan 2021 00:53:32
	(b) (4)	

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 '1'	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) (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) (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) (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) (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) (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 '1'	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) (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) (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) (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) (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 '1'	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) (b) (4), (b) (6)	05 Nov 2020 17:54:20
User entered '09 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:51:57

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID-19 Contact

Generated On: 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) (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

[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) (b) (4)	14 Oct 2020 22:51:57

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)'	(b) (4) 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

[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) (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

[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'	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

[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
User entered '36.9' C	(b) (4) 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

[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
User entered 'None (None)'	(b) (4) 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

[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
User entered 'Mild (Mild)'	(b) (4) 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

[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
User entered 'None (None)'	(b) (4) 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

[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) (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

[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
User entered 'None (None)'	(b) (4) 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

[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
User entered 'None (None)'	(b) (4) 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

[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
User entered 'None (None)'	(b) (4) 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

[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
User entered 'Moderate (Moderate)'	(b) (4) 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

[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
User entered 'None (None)'	(b) (4) 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

[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) (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

[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
User entered 'Mild (Mild)'	(b) (4) 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

[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
User entered 'None (None)'	(b) (4) 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

[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) (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

[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
User entered 'None (None)'	(b) (4) 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

[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
User entered 'None (None)'	(b) (4) 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

[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
User entered 'None (None)'	(b) (4) Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:53:16

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)'	(b) (4) Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:52:21

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 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) (b) (4)	04 Nov 2020 18:52:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 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'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:52:21

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 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) (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

[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) (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

[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) (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

[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) (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

[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) (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

[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.	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:52:21

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 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) (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

[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) (b) (4)	04 Nov 2020 18:52:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 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) (b) (4)	04 Nov 2020 18:52:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 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) (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

[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) (b) (4)	04 Nov 2020 18:52:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 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) (b) (4)	04 Nov 2020 18:52:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 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) (b) (4)	04 Nov 2020 18:52:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 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) (b) (4)	04 Nov 2020 18:52:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 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) (b) (4)	04 Nov 2020 18:52:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 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) (b) (4)	04 Nov 2020 18:52:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 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) (b) (4)	04 Nov 2020 18:52:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 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) (b) (4)	04 Nov 2020 18:52:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 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)'	(b) (4) Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:54:28

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 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) (b) (4)	04 Nov 2020 18:54:28

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 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) (b) (4)	04 Nov 2020 18:54:28

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 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) (b) (4)	04 Nov 2020 18:54:28

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 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

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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) (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

[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) (b) (4)	04 Nov 2020 18:54:28

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 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) (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

[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) (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

[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) (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

[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) (b) (4)	04 Nov 2020 18:54:28

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 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) (b) (4)	04 Nov 2020 18:54:28

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 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) (b) (4)	04 Nov 2020 18:54:28

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 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) (b) (4)	04 Nov 2020 18:54:28

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 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) (b) (4)	04 Nov 2020 18:54:28

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 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) (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

[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) (b) (4)	04 Nov 2020 18:54:28

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 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) (b) (4)	04 Nov 2020 18:54:28

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 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) (b) (4)	04 Nov 2020 18:54:28

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 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) (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

[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) (b) (4)	04 Nov 2020 18:54:28

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 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) (b) (4)	04 Nov 2020 18:54:28

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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)'	(b) (4) Jessica Satorie (b) (4)	04 Nov 2020 18:55:24
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 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 '10 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:55:24

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 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) (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

[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) (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

[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

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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) (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

[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) (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

[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) (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

[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) (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

[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) (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

[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) (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

[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) (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

[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) (b) (4)	04 Nov 2020 18:55:24

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 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) (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

[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) (b) (4)	04 Nov 2020 18:55:24

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 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) (b) (4)	04 Nov 2020 18:55:24

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 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) (b) (4)	04 Nov 2020 18:55:24

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 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) (b) (4)	04 Nov 2020 18:55:24

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 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) (b) (4)	04 Nov 2020 18:55:24

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 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) (b) (4)	04 Nov 2020 18:55:24

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 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) (b) (4)	04 Nov 2020 18:55:24

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 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) (b) (4)	04 Nov 2020 18:55:24

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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)'	(b) (4) Jessica Satorie (b) (4)	04 Nov 2020 18:56:18

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 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 '11 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:18

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 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) (b) (4)	04 Nov 2020 18:56:18

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 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) (b) (4)	04 Nov 2020 18:56:18

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 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

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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) (b) (4)	04 Nov 2020 18:56:18

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 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) (b) (4)	04 Nov 2020 18:56:18

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 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) (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) (b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:18

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 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) (b) (4)	04 Nov 2020 18:56:18

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 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) (b) (4)	04 Nov 2020 18:56:18

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 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) (b) (4)	04 Nov 2020 18:56:18

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Form: Symptom Log (5)

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[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) (b) (4)	04 Nov 2020 18:56:18

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 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) (b) (4)	04 Nov 2020 18:56:18

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 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) (b) (4)	04 Nov 2020 18:56:18

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 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) (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) (b) (4)	04 Nov 2020 18:56:18

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 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) (b) (4)	04 Nov 2020 18:56:18

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 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) (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

[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) (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

[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) (b) (4)	04 Nov 2020 18:56:18

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 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) (b) (4)	04 Nov 2020 18:56:18

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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)'	(b) (4) Jessica Satorie (b) (4)	04 Nov 2020 18:56:44
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 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 '12 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:56:44

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 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) (b) (4)	04 Nov 2020 18:56:44

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 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) (b) (4)	04 Nov 2020 18:56:44

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 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) (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

[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) (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) (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

[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) (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

[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) (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

[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) (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

[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) (b) (4)	04 Nov 2020 18:56:44

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 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) (b) (4)	04 Nov 2020 18:56:44

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 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) (b) (4)	04 Nov 2020 18:56:44

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 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) (b) (4)	04 Nov 2020 18:56:44

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 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) (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

[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) (b) (4)	04 Nov 2020 18:56:44

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 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) (b) (4)	04 Nov 2020 18:56:44

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

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[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) (b) (4)	04 Nov 2020 18:56:44

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 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) (b) (4)	04 Nov 2020 18:56:44

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 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) (b) (4)	04 Nov 2020 18:56:44

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 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) (b) (4)	04 Nov 2020 18:56:44

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)'	(b) (4) Jessica Satorie (b) (4)	04 Nov 2020 18:57:19

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 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) (b) (4)	04 Nov 2020 18:57:19

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

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[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) (b) (4)	04 Nov 2020 18:57:19

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 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) (b) (4)	04 Nov 2020 18:57:19

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 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

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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) (b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '97.1' F	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:57:19

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 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) (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) (b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:57:19

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 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) (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

[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) (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

[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) (b) (4)	04 Nov 2020 18:57:19

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 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) (b) (4)	04 Nov 2020 18:57:19

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 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) (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

[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) (b) (4)	04 Nov 2020 18:57:19

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 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) (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 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) (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) (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

[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) (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

[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) (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

[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) (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

[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) (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

[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) (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)'	(b) (4) 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) (b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered '14 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:01

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 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) (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) (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 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) (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

[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) (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

[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) (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

[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) (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

[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) (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

[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) (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) (b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:01

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 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) (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

[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) (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

[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) (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

[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) (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) (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

[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) (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

[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) (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

[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) (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

[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) (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

[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) (b) (4)	04 Nov 2020 18:58:01

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)'	(b) (4) Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:40

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 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 '15 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:40

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 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) (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

[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) (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

[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

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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) (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

[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) (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

[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) (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

[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) (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

[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) (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

[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) (b) (4)	04 Nov 2020 18:58:40

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 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) (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

[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) (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) (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 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) (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) (b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:58:40

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 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) (b) (4)	04 Nov 2020 18:58:40

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 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) (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

[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) (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

[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) (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

[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) (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

[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) (b) (4)	04 Nov 2020 18:58:40

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)'	(b) (4) Jessica Satorie (b) (4)	04 Nov 2020 18:59:36
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 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 '16 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:59:36

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 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) (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) (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 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) (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

[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) (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

[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) (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

[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) (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) (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

[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) (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

[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) (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

[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) (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) (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 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) (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) (b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:59:36

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

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[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) (b) (4)	04 Nov 2020 18:59:36

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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) (b) (4)	04 Nov 2020 18:59:36

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

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[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) (b) (4)	04 Nov 2020 18:59:36

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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) (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

[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) (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

[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) (b) (4)	04 Nov 2020 18:59:36

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)'	(b) (4) Jessica Satorie (b) (4)	04 Nov 2020 19:00:05
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 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) (b) (4)	04 Nov 2020 19:00:05

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 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) (b) (4)	04 Nov 2020 19:00:05

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 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) (b) (4)	04 Nov 2020 19:00:05

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 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) (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

[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) (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

[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) (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

[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) (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

[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) (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

[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) (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) (b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:00:05

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 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) (b) (4)	04 Nov 2020 19:00:05

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 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) (b) (4)	04 Nov 2020 19:00:05

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 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) (b) (4)	04 Nov 2020 19:00:05

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 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) (b) (4)	04 Nov 2020 19:00:05

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 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) (b) (4)	04 Nov 2020 19:00:05

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 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) (b) (4)	04 Nov 2020 19:00:05

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 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) (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

[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) (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

[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) (b) (4)	04 Nov 2020 19:00:05

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 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) (b) (4)	04 Nov 2020 19:00:05

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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)'	(b) (4) Jessica Satorie (b) (4)	04 Nov 2020 19:00:37
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 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 '18 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:00:37

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 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) (b) (4)	04 Nov 2020 19:00:37

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 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) (b) (4)	04 Nov 2020 19:00:37

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 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

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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) (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

[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) (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

[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) (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

[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) (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

[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) (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

[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) (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) (b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:00:37

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 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) (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

[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) (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 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) (b) (4)	04 Nov 2020 19:00:37

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 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) (b) (4)	04 Nov 2020 19:00:37

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 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) (b) (4)	04 Nov 2020 19:00:37

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 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) (b) (4)	04 Nov 2020 19:00:37

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

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[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) (b) (4)	04 Nov 2020 19:00:37

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 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) (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

[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) (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

[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) (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)'	(b) (4) Jessica Satorie (b) (4)	04 Nov 2020 19:03:43
	(b) (4)	

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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) (b) (4)	04 Nov 2020 19:03:43

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 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) (b) (4)	04 Nov 2020 19:03:43

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 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) (b) (4)	04 Nov 2020 19:03:43

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 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

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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) (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

[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) (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

[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) (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

[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) (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

[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) (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

[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) (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

[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) (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

[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) (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

[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) (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 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) (b) (4)	04 Nov 2020 19:03:43

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 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) (b) (4)	04 Nov 2020 19:03:43

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 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) (b) (4)	04 Nov 2020 19:03:43

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 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) (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

[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) (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

[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) (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

[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) (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

[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) (b) (4)	04 Nov 2020 19:03:43

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)'	(b) (4) 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

[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) (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

[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) (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) (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 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) (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

[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) (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

[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) (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

[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) (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

[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) (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

[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) (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

[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) (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

[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) (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

[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) (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 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) (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) (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

[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) (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

[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) (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

[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) (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

[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) (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

[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) (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

[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) (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)'	(b) (4) 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

[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 '21 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:05:13

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 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) (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) (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 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) (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

[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) (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

[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) (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

[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) (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) (b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:05:13

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 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) (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

[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) (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

[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) (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) (b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:05:13

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 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) (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) (b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:05:13

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 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) (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

[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) (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

[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) (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

[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) (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

[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) (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

[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) (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:	(b) (4)	
Data Entry Error	Jessica Satorie (b) (4)	05 Nov 2020 22:42:44
User entered 'Day 17 (Day 17)'	(b) (4)	
	Jessica Satorie (b) (4)	04 Nov 2020 19:05:53
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 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 '22 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:05:53

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 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) (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](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (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) (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) (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

[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) (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

[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) (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) (b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:05:53

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 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) (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

[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) (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

[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) (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

[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) (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

[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) (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 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) (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) (b) (4), (b) (6)	05 Nov 2020 17:54:34
User entered 'None (None)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 19:05:53

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 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) (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

[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) (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

[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) (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

[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) (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

[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) (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

[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) (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) (4), (b) (6)	27 Oct 2020 19:38:10
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 07:13:56
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'confirmed positive' (Site from System).	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:03
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	14 Oct 2020 22:53:51
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:53:51

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 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) (b) (4), (b) (6)	27 Oct 2020 19:38:35
User entered '09 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:53:51

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.	(b) (4) 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 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) (b) (4), (b) (6)	27 Oct 2020 19:38:30
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:53:51

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 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.	(b) (4) 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

[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.	(b) (4) 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

[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 '1'	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 \geq 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) (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.	(b) (4) Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 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.	(b) (4) Jessica Satorie (b) (4)	14 Oct 2020 22:55:33

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 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.	(b) (4) Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 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)'	(b) (4) Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 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.	(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

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[Heart Rate](#)

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Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

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[Oxygen Saturation](#)

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

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[PaO2](#)

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[Did the subject have Respiratory failure?](#)

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

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[High-Flow Oxygen?](#)

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[Non-Invasive Ventilation?](#)

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[Mechanical Ventilation?](#)

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[ECMO?](#)

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

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[Evidence of Shock Requires Vasopressors](#)

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[Acute Renal Dysfunction?](#)

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[Hepatic Dysfunction?](#)

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[Neurologic Dysfunction?](#)

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[Clinical Evidence](#)

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[Admission to an intensive care unit due to SARS-CoV-2](#)

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[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.	(b) (4) Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:55:33

US3002302

Folder: Covid-19 Assessment 09 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 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	Jessica Satorie (b) (4)	26 Feb 2021 17:30:21
User signature succeeded.	(b) (4) 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)'	Jessica Satorie (b) (4) (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) (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

[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) (b) (4), (b) (6)	05 Nov 2020 17:56:52
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 17:33:23

US3002302

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 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) (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

[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) (b) (4), (b) (6)	05 Nov 2020 17:56:52
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 17:33:23

US3002302

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 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 '15 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 17:33:23

US3002302

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 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) (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

[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 '17 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 17:33:23

US3002302

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 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) (b) (4), (b) (6)	05 Nov 2020 17:56:52
User entered '22 Oct 2020'	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 17:33:23

US3002302

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 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)	05 Jan 2021 16:58:29
User entered '29 Oct 2020' reason for change: Data Entry Error	Kimberly Mueller (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)	05 Jan 2021 00:13:42
User entered '27 Oct 2020' 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 empty.	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

[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.	(b) (4) Jessica Satorie (b) (4)	26 Feb 2021 17:32:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) 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	(b) (4) 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
	(b) (4)	

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) (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

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) (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

[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) (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

[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) (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

[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
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:55:58
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) (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

[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) (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

[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) (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

[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) (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

[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) (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

[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) (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

[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) (b) (4)	05 Nov 2020 22:20:41

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) (b) (4)	05 Nov 2020 22:20:41

US3002302

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 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) (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) (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) (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) (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) (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) (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) (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) (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) (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) (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) (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) (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, HLT: 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	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) (6)	06 Nov 2020 15:33:40
User coded data point as SOC: Infections and infestations, HLT: Infections - pathogen unspecified, HLT: Dental and oral soft tissue infections, PT: Tooth abscess, LLT: Tooth abscess - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 23:00:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 23:00:17
Data point term sent to Coder	System	14 Oct 2020 22:59:53
User entered 'Tooth Abcess'	Jessica Satorie (b) (4)	14 Oct 2020 22:59:43

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)'	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

[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) (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

[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) (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 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) (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 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) (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.	(b) (4) 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

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) (4), (b) (6)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 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) (4), (b) (6)	06 Nov 2020 15:33:40
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 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) (b) (4)	14 Oct 2020 22:59:43

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) (b) (4)	14 Oct 2020 22:59:43

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) (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

[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) (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 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) (4), (b) (6)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 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) (4), (b) (6)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 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) (b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 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) (b) (4), (b) (6)	06 Nov 2020 15:33:40
User entered empty.	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 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

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Folder: Adverse Events

Form: Adverse Events (1)

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[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) (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

[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) (b) (4)	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

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[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)

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[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) (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)

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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

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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) (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 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.	(b) (4) Jessica Satorie (b) (4)	19 Nov 2020 22:45:22
User entered '1' reason for change: Data Entry Error	(b) (4) Jessica Satorie (b) (4)	19 Nov 2020 22:45:22
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)

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[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

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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) (b) (4)	14 Oct 2020 22:59:43

US3002302

Folder: Adverse Events

Form: Adverse Events (1)

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[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) (b) (4)	14 Oct 2020 22:59:43

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

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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 'USA-US005-2020-mRNA-1273-P301000005'	System	15 Oct 2020 12:32:26
User entered 'New'	(b) (4), (b) (6)	15 Oct 2020 12:32:26

US3002302

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 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) (b) (4)	14 Oct 2020 23:07:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 23:07:23
Data point term sent to Coder	System	14 Oct 2020 23:05:59
User entered 'Covid-19'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 23:05:12

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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Folder: Adverse Events

Form: Adverse Events (2)

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[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)

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[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

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Folder: Adverse Events

Form: Adverse Events (2)

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[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

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Folder: Adverse Events

Form: Adverse Events (2)

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[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

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Folder: Adverse Events

Form: Adverse Events (2)

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[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

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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 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 18:23:31
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

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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) (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) (b) (4)	14 Oct 2020 23:05:12

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Folder: Adverse Events

Form: Adverse Events (2)

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[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 '1'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 23:05:12

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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

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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) (b) (4)	04 Nov 2020 18:26:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jessica Satorie (b) (4) (b) (4)	04 Nov 2020 18:16:34
User opened query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 17:01:18
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessica Satorie (b) (4) (b) (4)	14 Oct 2020 23:05:12

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Folder: Adverse Events

Form: Adverse Events (2)

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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

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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

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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)	
User opened query 'PV Query: Please provide the results of the Immunologic Assessment blood sample.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 19:23:59
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 17:02:17
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 17:01:41
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 17:01:30
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 17:00:48
	Jessica Satorie (b) (4)	14 Oct 2020 23:05:12
	(b) (4)	

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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

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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

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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

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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, HLG: 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. DataPoint Verified.	Coder Import (b) (4) (b) (4) (b) (4), (b) (6)	29 Mar 2021 10:11:29 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 DataPoint Un-verified.	System Kimberly Mueller (b) (4) (b) (4)	24 Mar 2021 22:08:38 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 DataPoint Verified.	Kimberly Mueller (b) (4) (b) (4) (b) (4), (b) (6)	24 Mar 2021 22:08:05 22 Mar 2021 15:12:48
User coded data point as SOC: Product issues, HLG: 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. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System (b) (4), (b) (6)	02 Mar 2021 21:52:46 26 Feb 2021 20:49:07 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, HLG: 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. Data point term sent to Coder User entered 'Dislodged IUD'	Coder Import (b) (4) (b) (4) System (b) (4), (b) (6)	22 Feb 2021 23:31:03 22 Feb 2021 20:25:28 22 Feb 2021 20:24:38

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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) (4), (b) (6)	22 Mar 2021 15:12:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 20:24:38

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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) (4), (b) (6)	22 Mar 2021 15:12:48
User entered 'No (N)'	(b) (4), (b) (6)	22 Feb 2021 20:24:38

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Folder: Adverse Events

Form: Adverse Events (3)

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[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) (4), (b) (6)	22 Mar 2021 15:12:48
User entered 'No (N)'	(b) (4), (b) (6)	22 Feb 2021 20:24:38

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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

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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) (4), (b) (6)	22 Mar 2021 15:12:48
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 20:24:38

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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

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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

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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

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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) (4), (b) (6)	22 Mar 2021 15:12:48
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 20:24:38

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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

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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) (b) (4), (b) (6)	22 Mar 2021 15:12:48
User closed query 'Data is required. Please complete.' (Site from System).	System	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	(b) (4), (b) (6)	26 Feb 2021 20:48:38
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Feb 2021 20:24:38
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 20:24:38

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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) (4), (b) (6)	22 Mar 2021 15:12:48
User entered 'No (N)'	(b) (4), (b) (6)	22 Feb 2021 20:24:38

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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) (4), (b) (6)	22 Mar 2021 15:12:48
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 20:24:38

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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) (4), (b) (6)	22 Mar 2021 15:12:48
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 20:24:38

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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) (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) (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) (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) (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) (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) (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) (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) (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) (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) (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) (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) (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) (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). User signature succeeded.	(b) (4), (b) (6) Brandon Essink (b) (4)	30 Mar 2021 08:07:40 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). DataPoint Verified.	Kimberly Mueller (b) (4) (b) (4)	24 Mar 2021 21:13:29 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). User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	28 Feb 2021 01:39:05 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) (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) (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 '1'	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)	11 Nov 2020 01:23:17
Query 'Per ETRTR: Please confirm and update accordingly whether Medication was dosed for AE COVID-19, thanks.' answered with 'Sudafed PE taken for Covid 19' (Site from CRA).	Jessica Satorie (b) (4)	09 Nov 2020 23:38:29
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:57:26
User opened query 'Per ETRTR: Please confirm and update accordingly whether Medication was dosed for AE COVID-19, thanks.' (Site from CRA).	(b) (4), (b) (6)	16 Oct 2020 19:11:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 17:04:35

US3002302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 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.	Coder Import (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)'	(b) (4) Jessica Satorie (b) (4)	04 Nov 2020 18:25:21
	(b) (4)	

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'	(b) (4) 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 '1'	(b) (4) 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)'	(b) (4) 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)'	(b) (4) Jessica Satorie (b) (4)	04 Nov 2020 18:25:21
	(b) (4)	

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.	(b) (4) Jessica Satorie (b) (4)	04 Nov 2020 18:25:21
	(b) (4)	

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)'	(b) (4) Jessica Satorie (b) (4)	04 Nov 2020 18:25:21
	(b) (4)	

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.	(b) (4) Jessica Satorie (b) (4)	04 Nov 2020 18:25:21
	(b) (4)	

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	(b) (4)	
	Jessica Satorie (b) (4)	19 Nov 2020 16:16:29
User entered '07 Oct 2020'	(b) (4)	
	Jessica Satorie (b) (4)	04 Nov 2020 18:25:21
	(b) (4)	

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)'	(b) (4) Jessica Satorie (b) (4)	04 Nov 2020 18:25:21
	(b) (4)	

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	(b) (4)	19 Nov 2020 16:16:29
User entered '07 Oct 2020'	Jessica Satorie (b) (4)	04 Nov 2020 18:25:21
	(b) (4)	

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)'	(b) (4) 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)	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
User entered 'Yes (Y)'	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
DataPoint activated with code reason code Data required.	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
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
User entered 'endometrial hyperplasia prophylaxis'	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
DataPoint activated with code reason code Data required.	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
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
User entered '10'	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
DataPoint activated with code reason code Data required.	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
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
User entered 'mg (mg)'	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
DataPoint activated with code reason code Data required.	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
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
User entered empty.	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
DataPoint activated with code reason code Data required.	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
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
User entered 'other (OTHER)'	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
DataPoint activated with code reason code Data required.	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
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
User entered 'Day 1-14 of each month'	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
DataPoint activated with code reason code Data required.	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
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
User entered 'Oral (ORAL)'	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
DataPoint activated with code reason code Data required.	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
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
User entered empty.	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
DataPoint activated with code reason code Data required.	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
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
User entered '01 Feb 2021'	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
DataPoint activated with code reason code Data required.	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
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
User entered '0'	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
DataPoint activated with code reason code Data required.	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
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
User entered 'Yes (Y)'	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
DataPoint activated with code reason code Data required.	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
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
User entered empty.	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
DataPoint activated with code reason code Data required.	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
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
User entered 'No (N)'	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:12:28
DataPoint activated with code reason code Data required.	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 22:11:03
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)	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)	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)	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
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Jessica Satorie (b) (4)	05 Nov 2020 22:17:08
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'	(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

[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)'	(b) (4) 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.	(b) (4) Kimberly Mueller (b) (4)	24 Mar 2021 21:14:54
	(b) (4)	

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).	(b) (4) 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.	(b) (4) 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 '1'	(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 '1'	(b) (4) (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 '1'	(b) (4) (b) (4), (b) (6)	21 Nov 2020 15:52:04