

US3002259 (Prod: Meridian Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:51:34

All time stamps listed in this document are displayed in GMT

US3002259

Form: Participant Creation

Data signed: (b) (4) 15 Feb 2021 12:36:31

Generated On: 09 Jun 2021 14:51:34

[Participant ID](#)

US3002259

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

US3002259

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 12:36:33

Generated On: 09 Jun 2021 14:51:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

Date of Birth (MMM yyyy)	(b) (6) 1955
Age	64
Age Units	YEARS
Age (Derived)	64
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 12:36:33

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Date of Informed Consent (<i>dd MMM yyyy</i>)	08 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 12:36:33

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 12:36:33

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 12:36:33

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Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 12:36:33

Generated On: 09 Jun 2021 14:51:34

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 12:36:33

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Condition	SMALL BOWEL OBSTRUCTION
Start date (dd MMM yyyy)	UN JUL 2019
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 JUL 2019
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JUL 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 12:36:33

Generated On: 09 Jun 2021 14:51:34

Condition	SMALL BOWEL RESECTION
Start date (dd MMM yyyy)	UN JUL 2019
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 JUL 2019
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JUL 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 12:36:33

Generated On: 09 Jun 2021 14:51:34

Condition	DIVERTICULOSIS
Start date (dd MMM yyyy)	UN JUL 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)	JUL 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 12:36:33

Generated On: 09 Jun 2021 14:51:34

Condition	ANXIETY
Start date (dd MMM yyyy)	UN JUN 2020
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)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 12:36:33

Generated On: 09 Jun 2021 14:51:34

Condition	CHRONIC BACK PAIN
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 (8)

Data signed: (b) (4) 15 Feb 2021 12:36:33

Generated On: 09 Jun 2021 14:51:34

Condition	BILATERAL LEG WEAKNESS
Start date (dd MMM yyyy)	UN JUN 2020
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)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 12:36:33

Generated On: 09 Jun 2021 14:51:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	08 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:50 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 10:50
Height (<i>xxx.x</i>)	177 cm
Weight (<i>xxx.x</i>)	104.8 kg
BMI (<i>xxx.x</i>)	33.45143 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 12:36:33

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 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: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 12:36:33

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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

REPAIRS OFFICE MACHINES

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

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 12:36:33

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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)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 12:36:33

Generated On: 09 Jun 2021 14:51:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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 12:36:33

Generated On: 09 Jun 2021 14:51:34

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

What was the participant's randomization number? 112391

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 12:36:33

Generated On: 09 Jun 2021 14:51:34

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 12:36:33

Generated On: 09 Jun 2021 14:51:34

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	10:50 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 10:50
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 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 12:36:33

Generated On: 09 Jun 2021 14:51:34

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 (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	12:23 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 12:23
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 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 12:36:33

Generated On: 09 Jun 2021 14:51:34

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: Exposure

Data signed: (b) (4) 15 Feb 2021 12:36:33

Generated On: 09 Jun 2021 14:51:34

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 08 SEP 2020

What was the treatment time? (00:00-23:59) 11:52 (24 HR)

Treatment Date and Time (derived) 08 SEP 2020 11:52

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 12:36:33

Generated On: 09 Jun 2021 14:51:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 SEP 2020
Collection time (00:00-23:59)	11:25 (24 HR)
Collection date and time (derived)	08 SEP 2020 11:25

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 12:36:33

Generated On: 09 Jun 2021 14:51:34

Collection date (dd MMM yyyy)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:17	08 SEP 2020 11:17
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 12:36:33

Generated On: 09 Jun 2021 14:51:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

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 98.6 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 08 SEP 2020 12:13

PC Open Date & Time 08 SEP 2020 12:12

PC Close Date & Time 08 SEP 2020 14:42

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 08 SEP 2020 15:38

PC Open Date & Time 08 SEP 2020 15:37

PC Close Date & Time 09 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:34

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 06:50

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 19:10

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 13:17

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 12:00

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 13:19

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 12:02

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 12:16

PC Open Date & Time

08 SEP 2020 12:12

PC Close Date & Time

08 SEP 2020 14:42

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 15:38

PC Open Date & Time

08 SEP 2020 15:37

PC Close Date & Time

09 SEP 2020 11:59

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 06:50

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 19:10

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 13:17

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 12:01

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 13:19

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 12:02

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

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 ☐

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 12:17
PC Open Date & Time	08 SEP 2020 12:12
PC Close Date & Time	08 SEP 2020 14:42

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

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 ☐

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 15:39
PC Open Date & Time	08 SEP 2020 15:37
PC Close Date & Time	09 SEP 2020 11:59

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:34

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 06:51
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:34

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 ☒

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:34

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 19:11
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:34

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 ☒

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EAB) (1725)

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:34

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 12:01
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

57 of 2418

EAB) (1725)

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:34

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 13:19
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

59 of 2418

EAB) (1725)

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:34

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 12:03
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3002259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3002259

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3002259

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3002259

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 12:36:33

Generated On: 09 Jun 2021 14:51:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 12:36:33

Generated On: 09 Jun 2021 14:51:34

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	06 OCT 2020
Time of assessment (00:00-23:59)	14:41 (24 HR)
Vital Signs Date and Time (derived)	06 OCT 2020 14:41
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 12:36:33

Generated On: 09 Jun 2021 14:51:34

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	06 OCT 2020
Time of assessment (00:00-23:59)	16:05 (24 HR)
Vital Signs Date and Time (derived)	06 OCT 2020 16:05
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3002259

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 12:36:33

Generated On: 09 Jun 2021 14:51:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 OCT 2020

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

US3002259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 12:36:33

Generated On: 09 Jun 2021 14:51:34

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) 06 OCT 2020

What was the treatment time? (00:00-23:59) 15:39 (24 HR)

Treatment Date and Time (derived) 06 OCT 2020 15:39

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

US3002259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 12:36:33

Generated On: 09 Jun 2021 14:51:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	06 OCT 2020
Collection time (00:00-23:59)	15:08 (24 HR)
Collection date and time (derived)	06 OCT 2020 15:08

US3002259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 12:36:33

Generated On: 09 Jun 2021 14:51:34

Collection date (dd MMM yyyy)			06 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:55	06 OCT 2020 14:55
Nasopharyngeal Swab 2	No		

US3002259

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 12:36:33

Generated On: 09 Jun 2021 14:51:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 16:05

PC Open Date & Time

06 OCT 2020 15:59

PC Close Date & Time

06 OCT 2020 18:29

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.7 °F

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

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

PC Time Stamp	06 OCT 2020 19:40
PC Open Date & Time	06 OCT 2020 19:24
PC Close Date & Time	07 OCT 2020 11:59

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:34

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 14:52

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

08 OCT 2020 12:00

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 OCT 2020 16:28

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

10 OCT 2020 13:22

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 OCT 2020 13:15

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 06:19

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 16:05

PC Open Date & Time

06 OCT 2020 15:59

PC Close Date & Time

06 OCT 2020 18:29

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

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

06 OCT 2020 19:40

PC Open Date & Time

06 OCT 2020 19:24

PC Close Date & Time

07 OCT 2020 11:59

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 14:52

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 12:01

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 OCT 2020 16:29

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 OCT 2020 13:22

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:34

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

11 OCT 2020 13:15

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 06:19

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

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 ☐

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

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

No ☒

Yes ☐

PC Time stamp	06 OCT 2020 16:06
PC Open Date & Time	06 OCT 2020 15:59
PC Close Date & Time	06 OCT 2020 18:29

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

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 ☐

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

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

No ☒

Yes ☐

PC Time stamp	06 OCT 2020 19:40
PC Open Date & Time	06 OCT 2020 19:24
PC Close Date & Time	07 OCT 2020 11:59

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:34

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 ☒

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:34

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 14:53
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:34

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 ☒

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:34

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 12:01
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:34

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 ☒

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:34

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 16:29
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:34

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 ☒

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:34

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 13:23
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:34

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 ☒

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:34

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 13:15
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:34

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 ☒

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3002259

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002259

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3002259

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002259

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3002259

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002259

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 12:36:33

Generated On: 09 Jun 2021 14:51:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3002259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 12:36:33

Generated On: 09 Jun 2021 14:51:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 NOV 2020
Time of assessment (00:00-23:59)	14:58 (24 HR)
Vital Signs Date and Time (derived)	02 NOV 2020 14:58
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3002259

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 12:36:33

Generated On: 09 Jun 2021 14:51:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 NOV 2020

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

US3002259

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 12:36:33

Generated On: 09 Jun 2021 14:51:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 NOV 2020
Collection time (00:00-23:59)	15:18 (24 HR)
Collection date and time (derived)	02 NOV 2020 15:18

US3002259

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 12:36:33

Generated On: 09 Jun 2021 14:51:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

08 NOV 2020 10:54:43

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3002259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 NOV 2020 09:14:47

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 09:52:12
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 09:16:22
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Please contact your study clinic immediately. Click below to confirm that you have read this 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	03 DEC 2020 09:15:40
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 13:11:04
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

19 DEC 2020 12:43:06

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 DEC 2020 07:53:10

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 12:01:24

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" 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"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	07 JAN 2021 11:05:37
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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	16 JAN 2021 12:46:47
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 08:04:53

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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	28 JAN 2021 07:59:24
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 FEB 2021 08:13:28

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

11 FEB 2021 09:39:26

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 11:12:26

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 14:32:40

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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	05 MAR 2021 18:27:29
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

13 MAR 2021 15:49:21

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 MAR 2021 09:39:01
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

25 MAR 2021 11:59:10

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 09:09:20

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 12:00:07

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 20:13:15

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 13:10:12

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 18:26:37

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 JUN 2021 00:01
Patient Cloud Close Date & Time	07 JUN 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUN 2021 00:01
Patient Cloud Close Date & Time	14 JUN 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 JUL 2021 00:01
Patient Cloud Close Date & Time	12 JUL 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

Patient Cloud Open Date & Time	12 AUG 2021 00:01
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Patient Cloud Close Date & Time	16 AUG 2021 23:59
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US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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 ☐

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 AUG 2021 00:01
Patient Cloud Close Date & Time	30 AUG 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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 ☐

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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 ☐

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2021 00:01
Patient Cloud Close Date & Time	25 OCT 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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 ☐

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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 ☐

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

Patient Cloud Open Date & Time	16 DEC 2021 00:01
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Patient Cloud Close Date & Time	20 DEC 2021 23:59
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US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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 ☐

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 FEB 2022 00:01
Patient Cloud Close Date & Time	21 FEB 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

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 ☐

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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 ☐

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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 ☐

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 APR 2022 00:01
Patient Cloud Close Date & Time	18 APR 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 607

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

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

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

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

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

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

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 MAY 2022 00:01
Patient Cloud Close Date & Time	16 MAY 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	28 JUL 2022 00:01
Patient Cloud Close Date & Time	01 AUG 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

Patient Cloud Open Date & Time	18 AUG 2022 00:01
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Patient Cloud Close Date & Time	22 AUG 2022 23:59
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US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

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 ☐

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

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 ☐

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 SEP 2022 00:01
Patient Cloud Close Date & Time	19 SEP 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 OCT 2022 00:01
Patient Cloud Close Date & Time	24 OCT 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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 ☐

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

[Patient Cloud Open Date & Time](#)

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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

Date and time of submission

Patient Cloud Open Date & Time	10 NOV 2022 00:01
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Patient Cloud Close Date & Time	14 NOV 2022 23:59
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US3002259

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:51:34

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		05 MAR 2021 18:27:41

US3002259

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3002259

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002259

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3002259

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002259

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:24:51

Generated On: 09 Jun 2021 14:51:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3002259

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:24:51

Generated On: 09 Jun 2021 14:51:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002259

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 12:43:35

Generated On: 09 Jun 2021 14:51:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3002259

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 12:43:35

Generated On: 09 Jun 2021 14:51:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002259

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 04:45:51

Generated On: 09 Jun 2021 14:51:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3002259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 15:01:20

Generated On: 09 Jun 2021 14:51:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	14:14 (24 HR)
Vital Signs Date and Time (derived)	26 MAR 2021 14:14
Temperature (<i>xxx.x</i>)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	81 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3002259

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 04:45:51

Generated On: 09 Jun 2021 14:51:34

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.

US3002259

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 04:45:51

Generated On: 09 Jun 2021 14:51:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 MAR 2021
Collection time (00:00-23:59)	14:16 (24 HR)
Collection date and time (derived)	26 MAR 2021 14:16

US3002259

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 04:45:51

Generated On: 09 Jun 2021 14:51:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002259

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3002259

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:51:34

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3002259

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

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

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

Visit date (dd MMM yyyy)	19 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3002259

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

Form: Unblinding

Data signed: (b) (4) 16 Mar 2021 12:51:00

Generated On: 09 Jun 2021 14:51:34

Date of updated informed consent (<i>dd MMM yyyy</i>)	19 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	19 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3002259

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Mar 2021 18:24:51

Generated On: 09 Jun 2021 14:51:34

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3002259

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 18:24:51

Generated On: 09 Jun 2021 14:51:34

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 JAN 2021
Time of assessment (00:00-23:59)	10:55 (24 HR)
Vital Signs Date and Time (derived)	20 JAN 2021 10:55
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3002259

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 18:24:51

Generated On: 09 Jun 2021 14:51:34

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 JAN 2021
Time of assessment (00:00-23:59)	11:49 (24 HR)
Vital Signs Date and Time (derived)	20 JAN 2021 11:49
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3002259

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

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 18:24:51

Generated On: 09 Jun 2021 14:51:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 JAN 2021

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

US3002259

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

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 20 JAN 2021

What was the treatment time? (00:00-23:59) 11:13 (24 HR)

Treatment Date and Time (derived) 20 JAN 2021 11:13

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

US3002259

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 JAN 2021

Collection time (00:00-23:59)

12:02 (24 HR)

Collection date and time (derived)

19 JAN 2021 12:02

US3002259

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 JAN 2021
Collection time (00:00 - 23:59)	12:04
Collection Date and Time (derived)	19 JAN 2021 12:04

US3002259

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

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002259

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:24:51

Generated On: 09 Jun 2021 14:51:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3002259

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:29:08

Generated On: 09 Jun 2021 14:51:34

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

US3002259

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 15:29:08

Generated On: 09 Jun 2021 14:51:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 15:29:08

Generated On: 09 Jun 2021 14:51:34

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 FEB 2021
Time of assessment (00:00-23:59)	13:02 (24 HR)
Vital Signs Date and Time (derived)	17 FEB 2021 13:02
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 15:29:08

Generated On: 09 Jun 2021 14:51:34

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 FEB 2021
Time of assessment (00:00-23:59)	14:13 (24 HR)
Vital Signs Date and Time (derived)	17 FEB 2021 14:13
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3002259

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 15:29:08

Generated On: 09 Jun 2021 14:51:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 FEB 2021

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

US3002259

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 15:29:08

Generated On: 09 Jun 2021 14:51:34

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 17 FEB 2021

What was the treatment time? (00:00-23:59) 13:43 (24 HR)

Treatment Date and Time (derived) 17 FEB 2021 13:43

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

US3002259

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:29:08

Generated On: 09 Jun 2021 14:51:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002259

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 19:08:03

Generated On: 09 Jun 2021 14:51:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3002259

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 04:45:51

Generated On: 09 Jun 2021 14:51:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002259

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 04:45:51

Generated On: 09 Jun 2021 14:51:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3002259

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 04:45:51

Generated On: 09 Jun 2021 14:51:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	14:14 (24 HR)
Vital Signs Date and Time (derived)	26 MAR 2021 14:14
Temperature (<i>xxx.x</i>)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	81 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3002259

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 04:45:51

Generated On: 09 Jun 2021 14:51:34

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.

US3002259

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 04:45:51

Generated On: 09 Jun 2021 14:51:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 MAR 2021
Collection time (00:00-23:59)	14:16 (24 HR)
Collection date and time (derived)	26 MAR 2021 14:16

US3002259

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 31 Mar 2021 20:36:05

Generated On: 09 Jun 2021 14:51:34

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

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 31 Mar 2021 20:36:05

Generated On: 09 Jun 2021 14:51:34

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 31 Mar 2021 20:36:05

Generated On: 09 Jun 2021 14:51:34

AEID	USA-US005-2020-MRNA-1273-P30 1000011
Adverse event	HYDROCEPHALUS
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)	06 DEC 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)	15 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	07 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	22 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 31 Mar 2021 20:36:05

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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 type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input checked="" 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	True
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	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 31 Mar 2021 20:36:05

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PT WAS ADMITTED TO
HOSPITAL FOR
HYDROCEPHALUS ON
07DEC2020 THOUGHT TO BE
RELATED TO
ENCEPHALOPATHY BROUGHT
ON BY COVID-19. SUBJECT
TESTED POSITIVE FOR
COVID-19 ON DECEMBER 4, 6,
AND 16. HE HAD VP SHUNT
PLACED DEC 15 WITH SOME
IMPROVEMENT OF WEAKNESS
AND GAIT. HE WAS ADMITTED
TO REHAB FACILITY ON DEC 22
FOR PT/OT AND WAS
DISCHARGED ON DEC 28. VIA
PHONE PT. STATES WEAKNESS
HAD TOTALLY RESOLVED ON
JAN 02, 2020.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 31 Mar 2021 20:36:05

Generated On: 09 Jun 2021 14:51:34

AEID	USA-US005-2020-MRNA-1273-P30 1000011
Adverse event	COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	04 DEC 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)	19 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 31 Mar 2021 20:36:05

Generated On: 09 Jun 2021 14:51:34

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 type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input checked="" 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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input type="radio"/>
	Recovered/Resolved with Sequelae <input checked="" type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	ATRIAL FIBRILLATION
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)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 31 Mar 2021 20:36:05

Generated On: 09 Jun 2021 14:51:34

AEID	
Adverse event	ATRIAL FIBRILLATION
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)	06 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 31 Mar 2021 20:36:05

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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	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input 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	POTENTIALLY TRIGGERED BY COVID 19 INFECTION PER TREATING PHYSICIAN
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 31 Mar 2021 20:36:05

Generated On: 09 Jun 2021 14:51:34

AEID	
Adverse event	URINARY RETENTION
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)	16 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
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 (5)

Data signed: (b) (4) 31 Mar 2021 20:36:05

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Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related ☒
Related ☐
Not Applicable ☐

Relationship to Study Procedure Not Related ☒
Related ☐
Not Applicable ☐

Action taken with investigational product None ☐
Dose Delayed ☐
Investigational Product ☐
Withdrawn ☐
Not Applicable ☒

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

Outcome Fatal ☐
Not Recovered/Not Resolved ☐
Recovered/Resolved ☐
Recovered/Resolved with ☐
Sequelae ☐
Recovering/Resolving ☒
Unknown ☐

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative SUBJECT HAD FOLEY CATHETER DURING HOSPITALIZATION FOR COVID-19/HYDROCEPHALUS DUE TO URINARY RETENTION, THEN SUCCESSFUL VOIDING TRIAL OUTPATIENT. HE CONTINUES ON FLOMAX.

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 31 Mar 2021 20:36:05

Generated On: 09 Jun 2021 14:51:34

Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 31 Mar 2021 20:36:05

Generated On: 09 Jun 2021 14:51:34

AEID	
Adverse event	VITAMIN B-12 DEFICIENCY
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)	16 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 31 Mar 2021 20:36:05

Generated On: 09 Jun 2021 14:51:34

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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" 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	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input 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) _____	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 31 Mar 2021 20:36:05

Generated On: 09 Jun 2021 14:51:34

AEID

Adverse event

WORSENING HYPERTENSION

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)

25 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

17 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 31 Mar 2021 20:36:05

Generated On: 09 Jun 2021 14:51:34

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input 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 _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 14 Apr 2021 19:58:12

Generated On: 09 Jun 2021 14:51:34

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 14 Apr 2021 19:58:12

Generated On: 09 Jun 2021 14:51:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 14 Apr 2021 19:58:12

Generated On: 09 Jun 2021 14:51:34

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 14 Apr 2021 19:58:12

Generated On: 09 Jun 2021 14:51:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 14 Apr 2021 19:58:12

Generated On: 09 Jun 2021 14:51:34

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 14 Apr 2021 19:58:12

Generated On: 09 Jun 2021 14:51:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 14 Apr 2021 19:58:12

Generated On: 09 Jun 2021 14:51:34

Name of Medication ESCITALOPRAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 14 Apr 2021 19:58:12

Generated On: 09 Jun 2021 14:51:34

	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 JUN 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 14 Apr 2021 19:58:12

Generated On: 09 Jun 2021 14:51:34

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication CHRONIC BACK PAIN

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 14 Apr 2021 19:58:12

Generated On: 09 Jun 2021 14:51:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 14 Apr 2021 19:58:12

Generated On: 09 Jun 2021 14:51:34

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 14 Apr 2021 19:58:12

Generated On: 09 Jun 2021 14:51:34

	Intramuscular	<input checked="" 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)		23 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		23 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 14 Apr 2021 19:58:12

Generated On: 09 Jun 2021 14:51:34

Name of Medication THIAMINE

Prophylaxis Yes ☐
No ☒

Indication VITAMIN B-12 DEFICIENCY

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 14 Apr 2021 19:58:12

Generated On: 09 Jun 2021 14:51:34

	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)	22 DEC 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 14 Apr 2021 19:58:12

Generated On: 09 Jun 2021 14:51:34

Name of Medication FLOMAX

Prophylaxis Yes ☐
No ☒

Indication URINARY RETENTION

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 14 Apr 2021 19:58:12

Generated On: 09 Jun 2021 14:51:34

	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)	22 DEC 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 14 Apr 2021 19:58:12

Generated On: 09 Jun 2021 14:51:34

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 14 Apr 2021 19:58:12

Generated On: 09 Jun 2021 14:51:34

	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)	25 DEC 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 14 Apr 2021 19:58:12

Generated On: 09 Jun 2021 14:51:34

Name of Medication SOLUMEDROL

Prophylaxis Yes ☐
No ☒

Indication HYDROCEPHALUS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 14 Apr 2021 19:58:12

Generated On: 09 Jun 2021 14:51:34

	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 checked="" 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)		10 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 14 Apr 2021 19:58:12

Generated On: 09 Jun 2021 14:51:34

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF
HYPERTENSION

Dose per administration 5

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 (11)

Data signed: (b) (4) 14 Apr 2021 19:58:12

Generated On: 09 Jun 2021 14:51:34

	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)	25 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 14 Apr 2021 19:58:12

Generated On: 09 Jun 2021 14:51:34

Name of Medication SHINGLES VACCINATION

Prophylaxis Yes ☒
No ☐

Indication SHINGLES PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 14 Apr 2021 19:58:12

Generated On: 09 Jun 2021 14:51:34

	Intramuscular	<input checked="" 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)		03 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		03 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 18:24:51

Generated On: 09 Jun 2021 14:51:34

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 18 Mar 2021 20:01:30

Generated On: 09 Jun 2021 14:51:34

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
15 DEC 2020	VENTRICULOPERITONEAL SHUNT PLACEMENT	Adverse Event	
15 DEC 2020	FOLEY CATHETER PLACEMENT	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:51:34

Date of dosing discontinuation (dd MMM yyyy)

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:51:34

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 ☐

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

SAEID	USA-US005-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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)	6

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

SAEID	USA-US005-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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)	6
Date of submission (Pre-filled from custom function)	09/DEC/2020 18:26
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

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

SAEID	USA-US005-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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)	6
Date of submission (Pre-filled from custom function)	09/DEC/2020 21:11
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

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

SAEID	USA-US005-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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)	6
Date of submission (Pre-filled from custom function)	11/DEC/2020 15:38
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

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form (4)

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

SAEID	USA-US005-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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)	6
Date of submission (Pre-filled from custom function)	07/JAN/2021 15:39
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

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form (5)

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

SAEID	USA-US005-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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)	6
Date of submission (Pre-filled from custom function)	08/JAN/2021 09:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form (6)

Data signed: (b) (4) 15 Feb 2021 12:36:32

Generated On: 09 Jun 2021 14:51:34

SAEID	USA-US005-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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)	6
Date of submission (Pre-filled from custom function)	08/JAN/2021 15:15
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

US3002259 (Prod: Meridian Clinical Research)

US3002259

Form: Participant Creation

Generated On: 09 Jun 2021 14:51:34

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'US3002259'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 15:59:55

US3002259

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:53:34

US3002259

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '08 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 15:59:56

US3002259

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

[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 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:53:34

US3002259

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered 'SCRN'	System	08 Sep 2020 17:53:34

US3002259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered (b) (6) 1955'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 15:59:57

US3002259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:34

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '64'	(b) (4), (b) (6)	08 Sep 2020 17:53:56

US3002259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:34

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered 'YEARS'	System	08 Sep 2020 17:53:56

US3002259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:34

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered '64'	System	08 Sep 2020 16:57:15

US3002259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:34

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:53:56

US3002259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:34

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:53:56

US3002259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:34

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'I'	(b) (4), (b) (6)	08 Sep 2020 17:53:56

US3002259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:34

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:53:56

US3002259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:34

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:53:56

US3002259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:34

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:53:56

US3002259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:34

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:53:56

US3002259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:53:56

US3002259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:34

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:53:56

US3002259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:34

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 17:53:56

US3002259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:34

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 17:53:56

US3002259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '08 Sep 2020'	Jessica Satorie (b) (4)	08 Sep 2020 16:57:15

US3002259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered 'Sep 2020'	System	08 Sep 2020 16:57:15

US3002259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered '2020'	System	08 Sep 2020 16:57:15

US3002259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:34

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Amendment 3 (3)'	Jessica Satorie (b) (4)	08 Sep 2020 16:57:15

US3002259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	08 Sep 2020 16:57:15

US3002259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Jessica Satorie (b) (4)	08 Sep 2020 16:57:15

US3002259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:34

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Jessica Satorie (b) (4)	08 Sep 2020 16:57:15

US3002259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:34

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	Jessica Satorie (b) (4)	08 Sep 2020 16:57:15

US3002259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:34

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 15:59:56

US3002259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:34

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered 'I'	System	08 Sep 2020 16:57:20

US3002259

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	08 Sep 2020 16:57:20

US3002259

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:51:34

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:54:41

US3002259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 17:56:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 17:56:45
Data point term sent to Coder	System	08 Sep 2020 17:55:32
User entered 'Hypertension'	(b) (4), (b) (6)	08 Sep 2020 17:54:56

US3002259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:54:56

US3002259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:54:56

US3002259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:54:56

US3002259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:34

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 17:54:56

US3002259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:54:56

US3002259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered 'Jan 2005'	System	08 Sep 2020 17:54:56

US3002259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered '2005'	System	08 Sep 2020 17:54:56

US3002259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered empty.	System	08 Sep 2020 17:54:56

US3002259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered empty.	System	08 Sep 2020 17:54:56

US3002259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 17:56:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 17:56:45
Data point term sent to Coder	System	08 Sep 2020 17:55:32
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	08 Sep 2020 17:55:11

US3002259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:55:11

US3002259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:55:11

US3002259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:55:11

US3002259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:55:11

US3002259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:55:11

US3002259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered 'Jan 2005'	System	08 Sep 2020 17:55:11

US3002259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered '2005'	System	08 Sep 2020 17:55:11

US3002259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered empty.	System	08 Sep 2020 17:55:11

US3002259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered empty.	System	08 Sep 2020 17:55:11

US3002259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal stenosis and obstruction, HLT: Duodenal and small intestinal stenosis and obstruction, PT: Small intestinal obstruction, LLT: Small bowel obstruction - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 17:56:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 17:56:45
Data point term sent to Coder	System	08 Sep 2020 17:55:32
User entered 'Small bowel obstruction'	(b) (4), (b) (6)	08 Sep 2020 17:55:29

US3002259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'un Jul 2019'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:55:29

US3002259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 17:55:29

US3002259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:55:29

US3002259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'un Jul 2019'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:55:29

US3002259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:55:29

US3002259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered 'Jul 2019'	System	08 Sep 2020 17:55:29

US3002259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered '2019'	System	08 Sep 2020 17:55:29

US3002259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered 'Jul 2019'	System	08 Sep 2020 17:55:29

US3002259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered '2019'	System	08 Sep 2020 17:55:29

US3002259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Small intestine therapeutic procedures, PT: Small intestinal resection, LLT: Small bowel resection - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 17:57:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 17:57:46
Data point term sent to Coder	System	08 Sep 2020 17:56:33
User entered 'Small bowel resection'	(b) (4), (b) (6)	08 Sep 2020 17:55:46

US3002259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'un Jul 2019'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:55:46

US3002259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:55:46

US3002259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:55:46

US3002259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'un Jul 2019'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:55:46

US3002259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:55:46

US3002259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered 'Jul 2019'	System	08 Sep 2020 17:55:46

US3002259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered '2019'	System	08 Sep 2020 17:55:46

US3002259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered 'Jul 2019'	System	08 Sep 2020 17:55:46

US3002259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered '2019'	System	08 Sep 2020 17:55:46

US3002259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User coded data point as SOC: Gastrointestinal disorders, HLGT: Diverticular disorders, HLT: Diverticula, PT: Diverticulum, LLT: Diverticulosis - version MedDRA\\23.0.	Coder Import (b) (4)	12 Dec 2020 15:32:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Dec 2020 15:32:46
Data point term sent to Coder	System	12 Dec 2020 15:32:27
Coding entries removed.	Brandon Essink (b) (4)	12 Dec 2020 15:32:12
User entered 'DIVERTICULOSIS' reason for change: Data Entry Error	Brandon Essink (b) (4)	12 Dec 2020 15:32:12
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diverticulitis, LLT: Diverticulitis - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 17:57:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 17:57:48
Data point term sent to Coder	System	08 Sep 2020 17:56:33
User entered 'Diverticulitis'	(b) (4), (b) (6)	08 Sep 2020 17:56:02

US3002259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'un Jul 2019'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:56:02

US3002259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:56:02

US3002259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:56:02

US3002259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:56:02

US3002259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:56:02

US3002259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered 'Jul 2019'	System	08 Sep 2020 17:56:02

US3002259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered '2019'	System	08 Sep 2020 17:56:02

US3002259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered empty.	System	08 Sep 2020 17:56:02

US3002259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered empty.	System	08 Sep 2020 17:56:02

US3002259

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 18:28:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 18:28:45
Data point term sent to Coder	System	09 Sep 2020 18:27:57
User entered 'Anxiety'	Tiffany Nemecek (b) (4)	09 Sep 2020 18:27:28

US3002259

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'un Jun 2020'	Tiffany Nemecek (b) (4)	09 Sep 2020 18:27:28

US3002259

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	Tiffany Nemecek (b) (4)	09 Sep 2020 18:27:28

US3002259

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4)	09 Sep 2020 18:27:28

US3002259

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Tiffany Nemecek (b) (4)	09 Sep 2020 18:27:28

US3002259

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	Tiffany Nemecek (b) (4)	09 Sep 2020 18:27:28

US3002259

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered 'Jun 2020'	System	09 Sep 2020 18:27:28

US3002259

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered '2020'	System	09 Sep 2020 18:27:28

US3002259

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered empty.	System	09 Sep 2020 18:27:28

US3002259

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered empty.	System	09 Sep 2020 18:27:28

US3002259

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:51:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 18:19:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 18:19:38
Data point term sent to Coder	System	11 Sep 2020 18:18:36
User entered 'chronic back pain'	Brandon Essink (b) (4)	11 Sep 2020 18:18:28

US3002259

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'un UNK 2015'	Brandon Essink (b) (4)	11 Sep 2020 18:18:28

US3002259

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:51:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	Brandon Essink (b) (4)	11 Sep 2020 18:18:28

US3002259

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:51:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	Brandon Essink (b) (4)	11 Sep 2020 18:18:28

US3002259

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:51:34

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Brandon Essink (b) (4)	11 Sep 2020 18:18:28

US3002259

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:51:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	Brandon Essink (b) (4)	11 Sep 2020 18:18:28

US3002259

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered 'Jan 2015'	System	11 Sep 2020 18:18:28

US3002259

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered '2015'	System	11 Sep 2020 18:18:28

US3002259

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered empty.	System	11 Sep 2020 18:18:28

US3002259

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered empty.	System	11 Sep 2020 18:18:28

US3002259

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:51:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle weakness conditions, PT: Muscular weakness, LLT: Lower extremities weakness of - version MedDRA\\23.0.	Coder Import (b) (4)	04 Dec 2020 15:59:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Dec 2020 15:59:59
Data point term sent to Coder	System	04 Dec 2020 15:59:32
User entered 'Bilateral leg weakness'	(b) (4), (b) (6)	04 Dec 2020 15:59:25

US3002259

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'un Jun 2020'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:59:25

US3002259

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:51:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:59:25

US3002259

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:51:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:59:25

US3002259

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 15:59:25

US3002259

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:51:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4), (b) (6)	04 Dec 2020 15:59:25

US3002259

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered 'Jun 2020'	System	04 Dec 2020 15:59:25

US3002259

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered '2020'	System	04 Dec 2020 15:59:25

US3002259

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered empty.	System	04 Dec 2020 15:59:25

US3002259

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered empty.	System	04 Dec 2020 15:59:25

US3002259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:56:37

US3002259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:56:37

US3002259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '10:50'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:56:37

US3002259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered '08 Sep 2020 10:50'	System	08 Sep 2020 17:56:37

US3002259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '177' cm	(b) (4)	08 Sep 2020 17:56:37
DataPoint set to visible.	System	08 Sep 2020 16:57:20

US3002259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '104.8' kg	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:56:37
DataPoint set to visible.	System	08 Sep 2020 16:57:20

US3002259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered '33.45143'	System	08 Sep 2020 17:56:37
DataPoint set to visible.	System	08 Sep 2020 16:57:20

US3002259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered 'kg/m2'	System	08 Sep 2020 17:56:37
DataPoint set to visible.	System	08 Sep 2020 16:57:20

US3002259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered missing code ND - Not Done.	(b) (4), (b) (6)	08 Sep 2020 17:56:37

US3002259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:56:37

US3002259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:56:37

US3002259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:56:37

US3002259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered 'bpm'	System	08 Sep 2020 17:56:37

US3002259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:56:37

US3002259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered 'breaths/min'	System	08 Sep 2020 17:56:37

US3002259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:56:37

US3002259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered 'mmHg'	System	08 Sep 2020 17:56:37

US3002259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:56:37

US3002259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User entered 'mmHg'	System	08 Sep 2020 17:56:37

US3002259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44

US3002259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44

US3002259

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:56:45

US3002259

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:56:45

US3002259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:34

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 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:54:22

US3002259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:34

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 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 17:54:22

US3002259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:34

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 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 17:54:22

US3002259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:34

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 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 17:54:22

US3002259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:34

[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 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:54:22

US3002259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:34

[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 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 17:54:22

US3002259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:34

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 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 17:54:22

US3002259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:34

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 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 17:54:22

US3002259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:34

[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 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:54:22

US3002259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:34

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 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 17:54:22

US3002259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:34

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 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 17:54:22

US3002259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:34

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:54:22

US3002259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Repairs office machines'	(b) (4), (b) (6)	08 Sep 2020 17:54:22

US3002259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:34

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'I'	(b) (4), (b) (6)	08 Sep 2020 17:54:22

US3002259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:54:22

US3002259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:34

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 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 17:54:22

US3002259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:34

[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 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:54:22

US3002259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:34

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 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 17:54:22

US3002259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:54:22

US3002259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:34

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 17:54:22

US3002259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:22:44
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 17:54:22

US3002259

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:56:55

US3002259

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:56:55

US3002259

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:56:55

US3002259

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'VISIT1'	System	08 Sep 2020 17:56:55

US3002259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '08 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 16:30:22

US3002259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '112391'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 16:30:22

US3002259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 16:30:22

US3002259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:34

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)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 17:57:02

US3002259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:34

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)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 17:57:02

US3002259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:57:02

US3002259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:34

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:57:02

US3002259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:34

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:57:02

US3002259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:34

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
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 06:38:54
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 17:14:07
User entered 'No (N)'	(b) (4), (b) (6)	02 Nov 2020 17:14:04
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 17:51:32
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:38:49
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:38:48

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:34

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:34

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '10:50'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered '08 Sep 2020 10:50'	System	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '36.7' C	(b) (4), (b) (6)	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '56'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'bpm'	System	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '13'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'breaths/min'	System	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '131'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'mmHg'	System	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '85'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'mmHg'	System	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:34

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '12:23'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered '08 Sep 2020 12:23'	System	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '78'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'bpm'	System	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '16'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'breaths/min'	System	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '126'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:57:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'mmHg'	System	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '76'	(b) (4), (b) (6)	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'mmHg'	System	08 Sep 2020 17:57:56

US3002259

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:58:11

US3002259

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:58:11

US3002259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	08 Sep 2020 16:57:38

US3002259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Jessica Satorie (b) (4)	08 Sep 2020 16:57:38

US3002259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

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)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Jessica Satorie (b) (4)	08 Sep 2020 16:57:38

US3002259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 16:57:38

US3002259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '08 Sep 2020'	Jessica Satorie (b) (4)	08 Sep 2020 16:57:38

US3002259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '11:52'	Jessica Satorie (b) (4)	08 Sep 2020 16:57:38

US3002259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered '08 Sep 2020 11:52'	System	08 Sep 2020 16:57:38

US3002259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Left Arm (LEFT ARM)'	Jessica Satorie (b) (4)	08 Sep 2020 16:57:38

US3002259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'ONCE'	System	08 Sep 2020 16:57:38

US3002259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 16:57:38

US3002259

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:58:25

US3002259

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:58:25

US3002259

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:34

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '11:25'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:58:25

US3002259

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered '08 Sep 2020 11:25'	System	08 Sep 2020 17:58:25

US3002259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:51:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:58:38

US3002259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:51:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	08 Sep 2020 17:58:38

US3002259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:51:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:58:38

US3002259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:51:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '11:17'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:58:38

US3002259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered '08 Sep 2020 11:17'	System	08 Sep 2020 17:58:38

US3002259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:51:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	08 Sep 2020 17:58:38

US3002259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:51:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:58:38

US3002259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:51:34

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:58:38

US3002259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered empty.	System	08 Sep 2020 17:58:38

US3002259

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:58:42

US3002259

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'I'	System	08 Sep 2020 17:58:42

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T12:13:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '97144c42-b4b0-4ea1-8175-d6e428d44860'	System	08 Sep 2020 17:13:54
User entered 'Yes (Y)'	System	08 Sep 2020 17:13:54

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T12:13:26', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '97144c42-b4b0-4ea1-8175-d6e428d44860'	System	08 Sep 2020 17:13:54
User entered '98.6'	System	08 Sep 2020 17:13:54

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T12:13:34', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '97144c42-b4b0-4ea1-8175-d6e428d44860'	System	08 Sep 2020 17:13:54
User entered 'Yes (Y)'	System	08 Sep 2020 17:13:54

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 05:07:08
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Patient stated took acetaminophen for chronic back pain not solicited reactions' (Site from System).	Brandon Essink (b) (4)	11 Sep 2020 18:20:34
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	08 Sep 2020 17:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T12:13:46', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '97144c42-b4b0-4ea1-8175-d6e428d44860'	System	08 Sep 2020 17:13:54
User entered '1'	System	08 Sep 2020 17:13:54

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T12:13:46', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '97144c42-b4b0-4ea1-8175-d6e428d44860'	System	08 Sep 2020 17:13:54
User entered '0'	System	08 Sep 2020 17:13:54

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T12:13:53', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '97144c42-b4b0-4ea1-8175-d6e428d44860'	System	08 Sep 2020 17:13:54
User entered '08 Sep 2020 12:13'	System	08 Sep 2020 17:13:54

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '08 Sep 2020 12:12'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '08 Sep 2020 14:42'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T15:37:39', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '4404ca99-a8da-4c32-a195-5c7e537d6bcb' User entered 'Yes (Y)'	System	08 Sep 2020 20:38:12
	System	08 Sep 2020 20:38:12

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T15:37:47', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '4404ca99-a8da-4c32-a195-5c7e537d6bcb' User entered '98.6'	System	08 Sep 2020 20:38:12
	System	08 Sep 2020 20:38:12

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T15:37:51', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '4404ca99-a8da-4c32-a195-5c7e537d6bcb' User entered 'Yes (Y)'	System	08 Sep 2020 20:38:12
	System	08 Sep 2020 20:38:12

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 05:07:15
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Patient takes acetaminophen for chronic back pain. Stated did not take medication for solicited reactions.' (Site from System).	Brandon Essink (b) (4) (b) (4)	11 Sep 2020 18:21:25
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	08 Sep 2020 20:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T15:37:59', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '4404ca99-a8da-4c32-a195-5c7e537d6bcb'	System	08 Sep 2020 20:38:12
User entered '1'	System	08 Sep 2020 20:38:12

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T15:37:59', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '4404ca99-a8da-4c32-a195-5c7e537d6bcb' User entered '0'	System	08 Sep 2020 20:38:12
	System	08 Sep 2020 20:38:12

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T15:38:08', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '4404ca99-a8da-4c32-a195-5c7e537d6bcb' User entered '08 Sep 2020 15:38'	System	08 Sep 2020 20:38:12
	System	08 Sep 2020 20:38:12

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '08 Sep 2020 15:37'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered 'Day 2'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T06:49:58', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '73876373-8708-44f0-a29e-9f478d87ffb1' User entered 'Yes (Y)'	System	10 Sep 2020 11:50:22
	System	10 Sep 2020 11:50:22

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T06:50:07', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '73876373-8708-44f0-a29e-9f478d87ffb1' User entered '98.7'	System	10 Sep 2020 11:50:22
	System	10 Sep 2020 11:50:22

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T06:50:12', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '73876373-8708-44f0-a29e-9f478d87ffb1'	System	10 Sep 2020 11:50:22
User entered 'No (N)'	System	10 Sep 2020 11:50:22

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T06:50:20', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '73876373-8708-44f0-a29e-9f478d87ffb1' User entered '10 Sep 2020 06:50'	System	10 Sep 2020 11:50:22
	System	10 Sep 2020 11:50:22

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered 'Day 3'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T19:10:08', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '34064ded-3d5f-42fe-bbba-64d491dd93c9' User entered 'Yes (Y)'	System	11 Sep 2020 00:10:30
	System	11 Sep 2020 00:10:30

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T19:10:18', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '34064ded-3d5f-42fe-bbba-64d491dd93c9' User entered '98.7'	System	11 Sep 2020 00:10:30
	System	11 Sep 2020 00:10:30

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T19:10:23', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '34064ded-3d5f-42fe-bbba-64d491dd93c9'	System	11 Sep 2020 00:10:30
User entered 'No (N)'	System	11 Sep 2020 00:10:30

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T19:10:27', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '34064ded-3d5f-42fe-bbba-64d491dd93c9'	System	11 Sep 2020 00:10:30
User entered '10 Sep 2020 19:10'	System	11 Sep 2020 00:10:30

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered 'Day 4'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-11T13:17:22', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '265eb7bb-44e9-4b6b-8044-c302cdc9dfd9' User entered 'Yes (Y)'	System	11 Sep 2020 18:17:44
	System	11 Sep 2020 18:17:44

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-11T13:17:30', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '265eb7bb-44e9-4b6b-8044-c302cdc9dfd9' User entered '98.8'	System	11 Sep 2020 18:17:44
	System	11 Sep 2020 18:17:44

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-11T13:17:33', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '265eb7bb-44e9-4b6b-8044-c302cdc9dfd9'	System	11 Sep 2020 18:17:44
User entered 'No (N)'	System	11 Sep 2020 18:17:44

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-11T13:17:37', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '265eb7bb-44e9-4b6b-8044-c302cdc9dfd9' User entered '11 Sep 2020 13:17'	System	11 Sep 2020 18:17:44
	System	11 Sep 2020 18:17:44

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered 'Day 5'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-12T12:00:31', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b8ffcfdf-ecbe-4142-b651-5eeec9380748' User entered 'Yes (Y)'	System	12 Sep 2020 17:01:16
	System	12 Sep 2020 17:01:16

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-12T12:00:39', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b8ffcfdf-ecbe-4142-b651-5eeec9380748' User entered '98.7'	System	12 Sep 2020 17:01:16
	System	12 Sep 2020 17:01:16

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-12T12:00:44', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b8ffcfdf-ecbe-4142-b651-5eeec9380748'	System	12 Sep 2020 17:01:16
User entered 'No (N)'	System	12 Sep 2020 17:01:16

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-12T12:00:48', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b8ffcfdf-ecbe-4142-b651-5eeec9380748'	System	12 Sep 2020 17:01:16
User entered '12 Sep 2020 12:00'	System	12 Sep 2020 17:01:16

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered 'Day 6'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-13T13:19:05', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b9f107ae-abf2-4152-aaf4-8bc8838c75ef' User entered 'Yes (Y)'	System	13 Sep 2020 18:19:29
	System	13 Sep 2020 18:19:29

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-13T13:19:11', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b9f107ae-abf2-4152-aaf4-8bc8838c75ef' User entered '98.6'	System	13 Sep 2020 18:19:29
	System	13 Sep 2020 18:19:29

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-13T13:19:15', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b9f107ae-abf2-4152-aaf4-8bc8838c75ef'	System	13 Sep 2020 18:19:29
User entered 'No (N)'	System	13 Sep 2020 18:19:29

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-13T13:19:19', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b9f107ae-abf2-4152-aaf4-8bc8838c75ef' User entered '13 Sep 2020 13:19'	System	13 Sep 2020 18:19:29
	System	13 Sep 2020 18:19:29

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered 'Day 7'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-14T12:02:10', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '32ba12f8-7830-455b-a430-61ba33ce64ae' User entered 'Yes (Y)'	System	14 Sep 2020 17:03:54
	System	14 Sep 2020 17:03:54

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-14T12:02:17', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '32ba12f8-7830-455b-a430-61ba33ce64ae' User entered '98.6'	System	14 Sep 2020 17:03:54
	System	14 Sep 2020 17:03:54

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-14T12:02:21', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '32ba12f8-7830-455b-a430-61ba33ce64ae'	System	14 Sep 2020 17:03:54
User entered 'No (N)'	System	14 Sep 2020 17:03:54

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-14T12:02:24', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '32ba12f8-7830-455b-a430-61ba33ce64ae'	System	14 Sep 2020 17:03:54
User entered '14 Sep 2020 12:02'	System	14 Sep 2020 17:03:54

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:41
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T12:14:28', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'bd31101e-e8dd-4d43-8227-c9e5fa06b2c4'	System	08 Sep 2020 17:16:17
User entered 'None (1)'	System	08 Sep 2020 17:16:17

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T12:15:59', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'bd31101e-e8dd-4d43-8227-c9e5fa06b2c4'	System	08 Sep 2020 17:16:17
User entered 'No (N)'	System	08 Sep 2020 17:16:17

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T12:16:04', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'bd31101e-e8dd-4d43-8227-c9e5fa06b2c4'	System	08 Sep 2020 17:16:17
User entered 'No (N)'	System	08 Sep 2020 17:16:17

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T12:16:11', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'bd31101e-e8dd-4d43-8227-c9e5fa06b2c4'	System	08 Sep 2020 17:16:17
User entered 'None (1)'	System	08 Sep 2020 17:16:17

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T12:16:15', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'bd31101e-e8dd-4d43-8227-c9e5fa06b2c4' User entered '08 Sep 2020 12:16'	System	08 Sep 2020 17:16:17
	System	08 Sep 2020 17:16:17

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '08 Sep 2020 12:12'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '08 Sep 2020 14:42'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T15:38:16', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '5f94adef-a868-4c2f-ab92-c1d4355f71b1' User entered 'None (1)'	System	08 Sep 2020 20:38:34
	System	08 Sep 2020 20:38:34

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T15:38:19', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '5f94adef-a868-4c2f-ab92-c1d4355f71b1' User entered 'No (N)'	System	08 Sep 2020 20:38:34
	System	08 Sep 2020 20:38:34

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T15:38:22', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '5f94adef-a868-4c2f-ab92-c1d4355f71b1' User entered 'No (N)'	System	08 Sep 2020 20:38:34
	System	08 Sep 2020 20:38:34

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T15:38:26', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '5f94adef-a868-4c2f-ab92-c1d4355f71b1' User entered 'None (1)'	System	08 Sep 2020 20:38:34
	System	08 Sep 2020 20:38:34

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T15:38:30', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '5f94adef-a868-4c2f-ab92-c1d4355f71b1' User entered '08 Sep 2020 15:38'	System	08 Sep 2020 20:38:34
	System	08 Sep 2020 20:38:34

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '08 Sep 2020 15:37'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered 'Day 2'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T06:50:25', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'fa88374a-48cf-478b-90c2-201d188a0fe5'	System	10 Sep 2020 11:50:43
User entered 'None (1)'	System	10 Sep 2020 11:50:43

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T06:50:29', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'fa88374a-48cf-478b-90c2-201d188a0fe5'	System	10 Sep 2020 11:50:43
User entered 'No (N)'	System	10 Sep 2020 11:50:43

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T06:50:32', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'fa88374a-48cf-478b-90c2-201d188a0fe5'	System	10 Sep 2020 11:50:43
User entered 'No (N)'	System	10 Sep 2020 11:50:43

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T06:50:38', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'fa88374a-48cf-478b-90c2-201d188a0fe5'	System	10 Sep 2020 11:50:43
User entered 'None (1)'	System	10 Sep 2020 11:50:43

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T06:50:41', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'fa88374a-48cf-478b-90c2-201d188a0fe5'	System	10 Sep 2020 11:50:43
User entered '10 Sep 2020 06:50'	System	10 Sep 2020 11:50:43

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered 'Day 3'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T19:10:33', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'a18fca28-1a92-46a7-a29f-51afe8e4d788'	System	11 Sep 2020 00:10:53
User entered 'None (1)'	System	11 Sep 2020 00:10:53

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T19:10:37', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'a18fca28-1a92-46a7-a29f-51afe8e4d788'	System	11 Sep 2020 00:10:53
User entered 'No (N)'	System	11 Sep 2020 00:10:53

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T19:10:41', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'a18fca28-1a92-46a7-a29f-51afe8e4d788'	System	11 Sep 2020 00:10:53
User entered 'No (N)'	System	11 Sep 2020 00:10:53

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T19:10:45', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'a18fca28-1a92-46a7-a29f-51afe8e4d788'	System	11 Sep 2020 00:10:53
User entered 'None (1)'	System	11 Sep 2020 00:10:53

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T19:10:49', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'a18fca28-1a92-46a7-a29f-51afe8e4d788'	System	11 Sep 2020 00:10:53
User entered '10 Sep 2020 19:10'	System	11 Sep 2020 00:10:53

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered 'Day 4'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-11T13:17:41', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '5faddc2b-35aa-4bf3-acbe-646ac0cba6f6' User entered 'None (1)'	System	11 Sep 2020 18:17:58
	System	11 Sep 2020 18:17:58

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-11T13:17:45', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '5faddc2b-35aa-4bf3-acbe-646ac0cba6f6' User entered 'No (N)'	System	11 Sep 2020 18:17:58
	System	11 Sep 2020 18:17:58

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-11T13:17:49', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '5faddc2b-35aa-4bf3-acbe-646ac0cba6f6'	System	11 Sep 2020 18:17:58
User entered 'No (N)'	System	11 Sep 2020 18:17:58

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-11T13:17:52', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '5faddc2b-35aa-4bf3-acbe-646ac0cba6f6' User entered 'None (1)'	System	11 Sep 2020 18:17:58
	System	11 Sep 2020 18:17:58

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-11T13:17:54', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '5faddc2b-35aa-4bf3-acbe-646ac0cba6f6' User entered '11 Sep 2020 13:17'	System	11 Sep 2020 18:17:58
	System	11 Sep 2020 18:17:58

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered 'Day 5'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-12T12:00:53', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '9800cadb-ec1e-4c27-898b-b738079eb776'	System	12 Sep 2020 17:01:43
User entered 'None (1)'	System	12 Sep 2020 17:01:43

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-12T12:00:57', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '9800cadb-ec1e-4c27-898b-b738079eb776'	System	12 Sep 2020 17:01:43
User entered 'No (N)'	System	12 Sep 2020 17:01:43

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-12T12:01:01', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '9800cadb-ec1e-4c27-898b-b738079eb776'	System	12 Sep 2020 17:01:43
User entered 'No (N)'	System	12 Sep 2020 17:01:43

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-12T12:01:04', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '9800cadb-ec1e-4c27-898b-b738079eb776'	System	12 Sep 2020 17:01:43
User entered 'None (1)'	System	12 Sep 2020 17:01:43

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-12T12:01:07', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '9800cadb-ec1e-4c27-898b-b738079eb776' User entered '12 Sep 2020 12:01'	System	12 Sep 2020 17:01:43
	System	12 Sep 2020 17:01:43

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered 'Day 6'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-13T13:19:23', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '0db8bec8-859a-4f8b-80f1-d7d67d4ed3d5' User entered 'None (1)'	System	13 Sep 2020 18:19:50
	System	13 Sep 2020 18:19:50

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-13T13:19:26', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '0db8bec8-859a-4f8b-80f1-d7d67d4ed3d5'	System	13 Sep 2020 18:19:50
User entered 'No (N)'	System	13 Sep 2020 18:19:50

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-13T13:19:29', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '0db8bec8-859a-4f8b-80f1-d7d67d4ed3d5'	System	13 Sep 2020 18:19:50
User entered 'No (N)'	System	13 Sep 2020 18:19:50

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-13T13:19:32', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '0db8bec8-859a-4f8b-80f1-d7d67d4ed3d5' User entered 'None (1)'	System	13 Sep 2020 18:19:50
	System	13 Sep 2020 18:19:50

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-13T13:19:34', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '0db8bec8-859a-4f8b-80f1-d7d67d4ed3d5'	System	13 Sep 2020 18:19:50
User entered '13 Sep 2020 13:19'	System	13 Sep 2020 18:19:50

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered 'Day 7'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-14T12:02:28', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '785517c3-d7e3-4c9b-8f2a-989aee355a20'	System	14 Sep 2020 17:04:18
User entered 'None (1)'	System	14 Sep 2020 17:04:18

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-14T12:02:33', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '785517c3-d7e3-4c9b-8f2a-989aee355a20'	System	14 Sep 2020 17:04:18
User entered 'No (N)'	System	14 Sep 2020 17:04:18

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-14T12:02:37', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '785517c3-d7e3-4c9b-8f2a-989aee355a20'	System	14 Sep 2020 17:04:18
User entered 'No (N)'	System	14 Sep 2020 17:04:18

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-14T12:02:40', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '785517c3-d7e3-4c9b-8f2a-989aee355a20'	System	14 Sep 2020 17:04:18
User entered 'None (1)'	System	14 Sep 2020 17:04:18

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-14T12:02:43', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '785517c3-d7e3-4c9b-8f2a-989aee355a20'	System	14 Sep 2020 17:04:18
User entered '14 Sep 2020 12:02'	System	14 Sep 2020 17:04:18

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:21:48
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T12:16:20', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'f0b9faf8-1655-45b2-9cf4-efc68f89d96e' User entered 'None (0)'	System	08 Sep 2020 17:17:08
	System	08 Sep 2020 17:17:08

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T12:16:25', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'f0b9faf8-1655-45b2-9cf4-efc68f89d96e' User entered 'None (0)'	System	08 Sep 2020 17:17:08
	System	08 Sep 2020 17:17:08

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T12:16:38', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'f0b9faf8-1655-45b2-9cf4-efc68f89d96e' User entered 'None (0)'	System	08 Sep 2020 17:17:08
	System	08 Sep 2020 17:17:08

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T12:16:42', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'f0b9faf8-1655-45b2-9cf4-efc68f89d96e' User entered 'None (0)'	System	08 Sep 2020 17:17:08
	System	08 Sep 2020 17:17:08

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T12:16:45', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'f0b9faf8-1655-45b2-9cf4-efc68f89d96e' User entered 'None (0)'	System	08 Sep 2020 17:17:08
	System	08 Sep 2020 17:17:08

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T12:16:48', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'f0b9faf8-1655-45b2-9cf4-efc68f89d96e'	System	08 Sep 2020 17:17:08
User entered 'None (0)'	System	08 Sep 2020 17:17:08

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

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)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T12:16:55', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'f0b9faf8-1655-45b2-9cf4-efc68f89d96e'	System	08 Sep 2020 17:17:08
User entered 'No (N)'	System	08 Sep 2020 17:17:08

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T12:17:05', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'f0b9faf8-1655-45b2-9cf4-efc68f89d96e'	System	08 Sep 2020 17:17:08
User entered '08 Sep 2020 12:17'	System	08 Sep 2020 17:17:08

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '08 Sep 2020 12:12'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '08 Sep 2020 14:42'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T15:38:36', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'f26047a0-d298-4be4-973d-1e4cc181688f' User entered 'None (0)'	System	08 Sep 2020 20:39:02
	System	08 Sep 2020 20:39:02

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T15:38:39', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'f26047a0-d298-4be4-973d-1e4cc181688f' User entered 'None (0)'	System	08 Sep 2020 20:39:02
	System	08 Sep 2020 20:39:02

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T15:38:42', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'f26047a0-d298-4be4-973d-1e4cc181688f' User entered 'None (0)'	System	08 Sep 2020 20:39:02
	System	08 Sep 2020 20:39:02

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T15:38:46', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'f26047a0-d298-4be4-973d-1e4cc181688f' User entered 'None (0)'	System	08 Sep 2020 20:39:02
	System	08 Sep 2020 20:39:02

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T15:38:49', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'f26047a0-d298-4be4-973d-1e4cc181688f' User entered 'None (0)'	System	08 Sep 2020 20:39:02
	System	08 Sep 2020 20:39:02

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T15:38:52', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'f26047a0-d298-4be4-973d-1e4cc181688f' User entered 'None (0)'	System	08 Sep 2020 20:39:02
	System	08 Sep 2020 20:39:02

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

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)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T15:38:58', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'f26047a0-d298-4be4-973d-1e4cc181688f'	System	08 Sep 2020 20:39:02
User entered 'No (N)'	System	08 Sep 2020 20:39:02

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-08T15:39:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'f26047a0-d298-4be4-973d-1e4cc181688f' User entered '08 Sep 2020 15:39'	System	08 Sep 2020 20:39:02
	System	08 Sep 2020 20:39:02

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '08 Sep 2020 15:37'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered 'Day 2'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T06:50:49', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '6ab604ba-66cf-4e01-b2ea-85c2fb3796e9'	System	10 Sep 2020 11:51:29
User entered 'None (0)'	System	10 Sep 2020 11:51:29

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T06:50:59', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '6ab604ba-66cf-4e01-b2ea-85c2fb3796e9'	System	10 Sep 2020 11:51:29
User entered 'No interference with activity (1)'	System	10 Sep 2020 11:51:29

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T06:51:07', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '6ab604ba-66cf-4e01-b2ea-85c2fb3796e9'	System	10 Sep 2020 11:51:29
User entered 'No interference with activity (1)'	System	10 Sep 2020 11:51:29

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T06:51:11', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '6ab604ba-66cf-4e01-b2ea-85c2fb3796e9'	System	10 Sep 2020 11:51:29
User entered 'No interference with activity (1)'	System	10 Sep 2020 11:51:29

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T06:51:14', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '6ab604ba-66cf-4e01-b2ea-85c2fb3796e9'	System	10 Sep 2020 11:51:29
User entered 'None (0)'	System	10 Sep 2020 11:51:29

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T06:51:18', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '6ab604ba-66cf-4e01-b2ea-85c2fb3796e9'	System	10 Sep 2020 11:51:29
User entered 'None (0)'	System	10 Sep 2020 11:51:29

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:34

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)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T06:51:21', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '6ab604ba-66cf-4e01-b2ea-85c2fb3796e9'	System	10 Sep 2020 11:51:29
User entered 'No (N)'	System	10 Sep 2020 11:51:29

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T06:51:24', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '6ab604ba-66cf-4e01-b2ea-85c2fb3796e9'	System	10 Sep 2020 11:51:29
User entered '10 Sep 2020 06:51'	System	10 Sep 2020 11:51:29

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered 'Day 3'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T19:10:57', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'a5929373-c826-4a41-ae81-3ff1344d8230'	System	11 Sep 2020 00:11:27
User entered 'No interference with activity (1)'	System	11 Sep 2020 00:11:27

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T19:11:01', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'a5929373-c826-4a41-ae81-3ff1344d8230'	System	11 Sep 2020 00:11:27
User entered 'No interference with activity (1)'	System	11 Sep 2020 00:11:27

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T19:11:05', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'a5929373-c826-4a41-ae81-3ff1344d8230'	System	11 Sep 2020 00:11:27
User entered 'No interference with activity (1)'	System	11 Sep 2020 00:11:27

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T19:11:08', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'a5929373-c826-4a41-ae81-3ff1344d8230'	System	11 Sep 2020 00:11:27
User entered 'No interference with activity (1)'	System	11 Sep 2020 00:11:27

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T19:11:12', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'a5929373-c826-4a41-ae81-3ff1344d8230'	System	11 Sep 2020 00:11:27
User entered 'None (0)'	System	11 Sep 2020 00:11:27

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T19:11:16', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'a5929373-c826-4a41-ae81-3ff1344d8230'	System	11 Sep 2020 00:11:27
User entered 'None (0)'	System	11 Sep 2020 00:11:27

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:34

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)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T19:11:19', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'a5929373-c826-4a41-ae81-3ff1344d8230'	System	11 Sep 2020 00:11:27
User entered 'No (N)'	System	11 Sep 2020 00:11:27

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-10T19:11:22', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'a5929373-c826-4a41-ae81-3ff1344d8230' User entered '10 Sep 2020 19:11'	System	11 Sep 2020 00:11:27
	System	11 Sep 2020 00:11:27

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered 'Day 4'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-11T13:18:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '75b24392-efa0-4a29-bd5e-bcd0647f61bb' User entered 'None (0)'	System	11 Sep 2020 18:18:36
	System	11 Sep 2020 18:18:36

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-11T13:18:04', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '75b24392-efa0-4a29-bd5e-bcd0647f61bb' User entered 'None (0)'	System	11 Sep 2020 18:18:36
	System	11 Sep 2020 18:18:36

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-11T13:18:12', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '75b24392-efa0-4a29-bd5e-bcd0647f61bb' User entered 'None (0)'	System	11 Sep 2020 18:18:36
	System	11 Sep 2020 18:18:36

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-11T13:18:19', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '75b24392-efa0-4a29-bd5e-bcd0647f61bb'	System	11 Sep 2020 18:18:36
User entered 'No interference with activity (1)'	System	11 Sep 2020 18:18:36

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-11T13:18:22', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '75b24392-efa0-4a29-bd5e-bcd0647f61bb' User entered 'None (0)'	System	11 Sep 2020 18:18:36
	System	11 Sep 2020 18:18:36

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-11T13:18:24', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '75b24392-efa0-4a29-bd5e-bcd0647f61bb' User entered 'None (0)'	System	11 Sep 2020 18:18:36
	System	11 Sep 2020 18:18:36

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:34

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)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-11T13:18:28', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '75b24392-efa0-4a29-bd5e-bcd0647f61bb' User entered 'No (N)'	System	11 Sep 2020 18:18:36
	System	11 Sep 2020 18:18:36

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-11T13:18:31', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '75b24392-efa0-4a29-bd5e-bcd0647f61bb' User entered '11 Sep 2020 13:18'	System	11 Sep 2020 18:18:36
	System	11 Sep 2020 18:18:36

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered 'Day 5'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-12T12:01:13', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '3d4086db-e203-4f17-8f44-0f2e44a54f1b' User entered 'None (0)'	System	12 Sep 2020 17:02:19
	System	12 Sep 2020 17:02:19

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-12T12:01:16', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '3d4086db-e203-4f17-8f44-0f2e44a54f1b' User entered 'None (0)'	System	12 Sep 2020 17:02:19
	System	12 Sep 2020 17:02:19

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-12T12:01:18', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '3d4086db-e203-4f17-8f44-0f2e44a54f1b' User entered 'None (0)'	System	12 Sep 2020 17:02:19
	System	12 Sep 2020 17:02:19

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-12T12:01:21', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '3d4086db-e203-4f17-8f44-0f2e44a54f1b' User entered 'None (0)'	System	12 Sep 2020 17:02:19
	System	12 Sep 2020 17:02:19

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-12T12:01:24', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '3d4086db-e203-4f17-8f44-0f2e44a54f1b' User entered 'None (0)'	System	12 Sep 2020 17:02:19
	System	12 Sep 2020 17:02:19

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-12T12:01:27', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '3d4086db-e203-4f17-8f44-0f2e44a54f1b' User entered 'None (0)'	System	12 Sep 2020 17:02:19
	System	12 Sep 2020 17:02:19

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:34

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)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-12T12:01:32', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '3d4086db-e203-4f17-8f44-0f2e44a54f1b'	System	12 Sep 2020 17:02:19
User entered 'No (N)'	System	12 Sep 2020 17:02:19

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-12T12:01:35', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '3d4086db-e203-4f17-8f44-0f2e44a54f1b' User entered '12 Sep 2020 12:01'	System	12 Sep 2020 17:02:19
	System	12 Sep 2020 17:02:19

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered 'Day 6'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-13T13:19:39', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'cc6702ba-f6b3-4993-8b5c-b8d3354dfbab' User entered 'None (0)'	System	13 Sep 2020 18:20:03
	System	13 Sep 2020 18:20:03

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-13T13:19:42', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'cc6702ba-f6b3-4993-8b5c-b8d3354dfbab' User entered 'None (0)'	System	13 Sep 2020 18:20:03
	System	13 Sep 2020 18:20:03

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-13T13:19:44', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'cc6702ba-f6b3-4993-8b5c-b8d3354dfbab' User entered 'None (0)'	System	13 Sep 2020 18:20:03
	System	13 Sep 2020 18:20:03

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-13T13:19:46', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'cc6702ba-f6b3-4993-8b5c-b8d3354dfbab' User entered 'None (0)'	System	13 Sep 2020 18:20:03
	System	13 Sep 2020 18:20:03

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-13T13:19:48', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'cc6702ba-f6b3-4993-8b5c-b8d3354dfbab' User entered 'None (0)'	System	13 Sep 2020 18:20:03
	System	13 Sep 2020 18:20:03

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-13T13:19:51', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'cc6702ba-f6b3-4993-8b5c-b8d3354dfbab' User entered 'None (0)'	System	13 Sep 2020 18:20:03
	System	13 Sep 2020 18:20:03

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:34

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)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-13T13:19:54', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'cc6702ba-f6b3-4993-8b5c-b8d3354dfbab'	System	13 Sep 2020 18:20:03
User entered 'No (N)'	System	13 Sep 2020 18:20:03

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-13T13:19:56', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'cc6702ba-f6b3-4993-8b5c-b8d3354dfbab' User entered '13 Sep 2020 13:19'	System	13 Sep 2020 18:20:03
	System	13 Sep 2020 18:20:03

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered 'Day 7'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-14T12:02:48', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b0a43ae6-eb4b-49ad-a37e-2909693fa11a' User entered 'None (0)'	System	14 Sep 2020 17:04:37
	System	14 Sep 2020 17:04:37

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-14T12:02:50', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b0a43ae6-eb4b-49ad-a37e-2909693fa11a' User entered 'None (0)'	System	14 Sep 2020 17:04:37
	System	14 Sep 2020 17:04:37

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-14T12:02:52', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b0a43ae6-eb4b-49ad-a37e-2909693fa11a' User entered 'None (0)'	System	14 Sep 2020 17:04:37
	System	14 Sep 2020 17:04:37

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-14T12:02:55', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b0a43ae6-eb4b-49ad-a37e-2909693fa11a' User entered 'None (0)'	System	14 Sep 2020 17:04:37
	System	14 Sep 2020 17:04:37

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-14T12:02:57', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b0a43ae6-eb4b-49ad-a37e-2909693fa11a' User entered 'None (0)'	System	14 Sep 2020 17:04:37
	System	14 Sep 2020 17:04:37

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-14T12:02:59', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b0a43ae6-eb4b-49ad-a37e-2909693fa11a' User entered 'None (0)'	System	14 Sep 2020 17:04:37
	System	14 Sep 2020 17:04:37

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:34

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)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-14T12:03:03', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b0a43ae6-eb4b-49ad-a37e-2909693fa11a'	System	14 Sep 2020 17:04:37
User entered 'No (N)'	System	14 Sep 2020 17:04:37

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-09-14T12:03:05', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b0a43ae6-eb4b-49ad-a37e-2909693fa11a' User entered '14 Sep 2020 12:03'	System	14 Sep 2020 17:04:37
	System	14 Sep 2020 17:04:37

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 16:57:38

US3002259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:10
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 16:57:38

US3002259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4)	23 Sep 2020 14:44:05

US3002259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '17 Sep 2020'	Tiffany Nemecek (b) (4)	23 Sep 2020 14:44:05

US3002259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Contact Made (CONTACT MADE)'	Tiffany Nemecek (b) (4)	23 Sep 2020 14:44:05

US3002259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Tiffany Nemecek (b) (4)	23 Sep 2020 14:44:05

US3002259

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4)	23 Sep 2020 14:44:10

US3002259

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'I'	System	23 Sep 2020 14:44:10

US3002259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4)	23 Sep 2020 14:44:20

US3002259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '22 Sep 2020'	Tiffany Nemecek (b) (4)	23 Sep 2020 14:44:20

US3002259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Contact Made (CONTACT MADE)'	Tiffany Nemecek (b) (4)	23 Sep 2020 14:44:20

US3002259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Tiffany Nemecek (b) (4)	23 Sep 2020 14:44:20

US3002259

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4)	23 Sep 2020 14:44:24

US3002259

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'I'	System	23 Sep 2020 14:44:24

US3002259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:24:43

US3002259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:24:43

US3002259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:24:43

US3002259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:24:43

US3002259

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	06 Oct 2020 20:42:18

US3002259

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'I'	System	06 Oct 2020 20:42:18

US3002259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:25:00

US3002259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '06 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:25:00

US3002259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:25:00

US3002259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'VISIT2'	System	07 Oct 2020 13:25:00

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '06 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '14:41'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered '06 Oct 2020 14:41'	System	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '37.2' C	(b) (4), (b) (6)	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '74'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'bpm'	System	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '15'	(b) (4), (b) (6)	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'breaths/min'	System	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '139'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'mmHg'	System	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '77'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'mmHg'	System	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '06 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '16:05'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered '06 Oct 2020 16:05'	System	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '37.0' C	(b) (4), (b) (6)	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '67'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'bpm'	System	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '14'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'breaths/min'	System	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '137'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'mmHg'	System	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '83'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'mmHg'	System	07 Oct 2020 13:25:54

US3002259

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:26:09

US3002259

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '06 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:26:09

US3002259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	06 Oct 2020 20:42:34

US3002259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Jessica Satorie (b) (4)	06 Oct 2020 20:42:34

US3002259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

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)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Jessica Satorie (b) (4)	06 Oct 2020 20:42:34

US3002259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'MRNA-1273 OR PLACEBO'	System	06 Oct 2020 20:42:34

US3002259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '06 Oct 2020'	Jessica Satorie (b) (4)	06 Oct 2020 20:42:34

US3002259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '15:39'	Jessica Satorie (b) (4)	06 Oct 2020 20:42:34

US3002259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered '06 Oct 2020 15:39'	System	06 Oct 2020 20:42:34

US3002259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Left Arm (LEFT ARM)'	Jessica Satorie (b) (4)	06 Oct 2020 20:42:34

US3002259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'ONCE'	System	06 Oct 2020 20:42:34

US3002259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'INTRAMUSCULAR'	System	06 Oct 2020 20:42:34

US3002259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:26:21

US3002259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '06 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:26:21

US3002259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:34

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '15:08'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:26:21

US3002259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered '06 Oct 2020 15:08'	System	07 Oct 2020 13:26:21

US3002259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:51:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '06 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:26:29

US3002259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:51:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	07 Oct 2020 13:26:29

US3002259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:51:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:26:29

US3002259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:51:34

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '14:55'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:26:29

US3002259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered '06 Oct 2020 14:55'	System	07 Oct 2020 13:26:29

US3002259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:51:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	07 Oct 2020 13:26:29

US3002259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:51:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:26:29

US3002259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:51:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:26:29

US3002259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered empty.	System	07 Oct 2020 13:26:29

US3002259

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:26:33

US3002259

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'I'	System	07 Oct 2020 13:26:33

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	06 Oct 2020 20:42:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T16:04:56', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'e84a9dec-a46a-4a80-9c29-86ff402d37ae' User entered 'Yes (Y)'	System	06 Oct 2020 21:05:19
	System	06 Oct 2020 21:05:19

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T16:05:05', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'e84a9dec-a46a-4a80-9c29-86ff402d37ae' User entered '98.8'	System	06 Oct 2020 21:05:19
	System	06 Oct 2020 21:05:19

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T16:05:10', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'e84a9dec-a46a-4a80-9c29-86ff402d37ae'	System	06 Oct 2020 21:05:19
User entered 'No (N)'	System	06 Oct 2020 21:05:19

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T16:05:16', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'e84a9dec-a46a-4a80-9c29-86ff402d37ae' User entered '06 Oct 2020 16:05'	System	06 Oct 2020 21:05:19
	System	06 Oct 2020 21:05:19

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '06 Oct 2020 15:59'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '06 Oct 2020 18:29'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	06 Oct 2020 20:42:34
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T19:39:49', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '0400af1a-b523-4ebf-9bea-bdac447c1e75'	System	07 Oct 2020 00:40:12
User entered 'Yes (Y)'	System	07 Oct 2020 00:40:12

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T19:39:58', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '0400af1a-b523-4ebf-9bea-bdac447c1e75'	System	07 Oct 2020 00:40:12
User entered '98.7'	System	07 Oct 2020 00:40:12

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T19:40:02', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '0400af1a-b523-4ebf-9bea-bdac447c1e75'	System	07 Oct 2020 00:40:12
User entered 'No (N)'	System	07 Oct 2020 00:40:12

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T19:40:08', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '0400af1a-b523-4ebf-9bea-bdac447c1e75'	System	07 Oct 2020 00:40:12
User entered '06 Oct 2020 19:40'	System	07 Oct 2020 00:40:12

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '06 Oct 2020 19:24'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	06 Oct 2020 20:42:34
User entered 'Day 2'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:34

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-07T14:51:51', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b6970c7c-67c5-4ae2-b82f-feb322096a08'	System	07 Oct 2020 19:52:21
User entered 'Yes (Y)'	System	07 Oct 2020 19:52:21

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-07T14:52:04', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b6970c7c-67c5-4ae2-b82f-feb322096a08'	System	07 Oct 2020 19:52:21
User entered '98.5'	System	07 Oct 2020 19:52:21

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-07T14:52:15', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b6970c7c-67c5-4ae2-b82f-feb322096a08'	System	07 Oct 2020 19:52:21
User entered 'No (N)'	System	07 Oct 2020 19:52:21

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-07T14:52:20', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b6970c7c-67c5-4ae2-b82f-feb322096a08' User entered '07 Oct 2020 14:52'	System	07 Oct 2020 19:52:21
	System	07 Oct 2020 19:52:21

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	06 Oct 2020 20:42:34
User entered 'Day 3'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-08T12:00:34', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '42f9994e-5942-4150-b37d-53d56117944f' User entered 'Yes (Y)'	System	08 Oct 2020 17:01:13
	System	08 Oct 2020 17:01:13

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-08T12:00:43', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '42f9994e-5942-4150-b37d-53d56117944f' User entered '98.5'	System	08 Oct 2020 17:01:13
	System	08 Oct 2020 17:01:13

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-08T12:00:47', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '42f9994e-5942-4150-b37d-53d56117944f'	System	08 Oct 2020 17:01:13
User entered 'No (N)'	System	08 Oct 2020 17:01:13

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-08T12:00:49', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '42f9994e-5942-4150-b37d-53d56117944f' User entered '08 Oct 2020 12:00'	System	08 Oct 2020 17:01:13
	System	08 Oct 2020 17:01:13

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	06 Oct 2020 20:42:34
User entered 'Day 4'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-09T16:28:27', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '2ba4ef63-ec0e-4c52-80af-8dcd77bc9421'	System	09 Oct 2020 21:28:50
User entered 'Yes (Y)'	System	09 Oct 2020 21:28:50

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-09T16:28:33', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '2ba4ef63-ec0e-4c52-80af-8dcd77bc9421' User entered '98.7'	System	09 Oct 2020 21:28:50
	System	09 Oct 2020 21:28:50

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-09T16:28:37', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '2ba4ef63-ec0e-4c52-80af-8dcd77bc9421'	System	09 Oct 2020 21:28:50
User entered 'No (N)'	System	09 Oct 2020 21:28:50

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-09T16:28:45', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '2ba4ef63-ec0e-4c52-80af-8dcd77bc9421' User entered '09 Oct 2020 16:28'	System	09 Oct 2020 21:28:50
	System	09 Oct 2020 21:28:50

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	06 Oct 2020 20:42:34
User entered 'Day 5'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-10T13:22:17', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'd4da08a9-75aa-42e6-984b-f118d20b4065' User entered 'Yes (Y)'	System	10 Oct 2020 18:22:39
	System	10 Oct 2020 18:22:39

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-10T13:22:27', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'd4da08a9-75aa-42e6-984b-f118d20b4065'	System	10 Oct 2020 18:22:39
User entered '98.5'	System	10 Oct 2020 18:22:39

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-10T13:22:31', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'd4da08a9-75aa-42e6-984b-f118d20b4065'	System	10 Oct 2020 18:22:39
User entered 'No (N)'	System	10 Oct 2020 18:22:39

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-10T13:22:34', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'd4da08a9-75aa-42e6-984b-f118d20b4065' User entered '10 Oct 2020 13:22'	System	10 Oct 2020 18:22:39
	System	10 Oct 2020 18:22:39

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	06 Oct 2020 20:42:34
User entered 'Day 6'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-11T13:14:47', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'f765f06c-e3fd-434b-ab0b-1dd7fd3ef8d6' User entered 'Yes (Y)'	System	11 Oct 2020 18:15:07
	System	11 Oct 2020 18:15:07

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-11T13:14:58', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'f765f06c-e3fd-434b-ab0b-1dd7fd3ef8d6'	System	11 Oct 2020 18:15:07
User entered '97.9'	System	11 Oct 2020 18:15:07

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-11T13:15:01', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'f765f06c-e3fd-434b-ab0b-1dd7fd3ef8d6'	System	11 Oct 2020 18:15:07
User entered 'No (N)'	System	11 Oct 2020 18:15:07

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-11T13:15:04', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'f765f06c-e3fd-434b-ab0b-1dd7fd3ef8d6' User entered '11 Oct 2020 13:15'	System	11 Oct 2020 18:15:07
	System	11 Oct 2020 18:15:07

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	06 Oct 2020 20:42:34
User entered 'Day 7'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-13T06:19:18', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'fbae26ac-71e6-48a3-a73b-e320d0660f63' User entered 'Yes (Y)'	System	13 Oct 2020 11:19:44
	System	13 Oct 2020 11:19:44

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-13T06:19:32', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'fbae26ac-71e6-48a3-a73b-e320d0660f63'	System	13 Oct 2020 11:19:44
User entered '97.5'	System	13 Oct 2020 11:19:44

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-13T06:19:37', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'fbae26ac-71e6-48a3-a73b-e320d0660f63'	System	13 Oct 2020 11:19:44
User entered 'No (N)'	System	13 Oct 2020 11:19:44

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-13T06:19:40', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'fbae26ac-71e6-48a3-a73b-e320d0660f63'	System	13 Oct 2020 11:19:44
User entered '13 Oct 2020 06:19'	System	13 Oct 2020 11:19:44

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:22:17
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	06 Oct 2020 20:42:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T16:05:33', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c2ecdda4-2f00-4eaf-8504-161af734a999'	System	06 Oct 2020 21:05:53
User entered 'None (1)'	System	06 Oct 2020 21:05:53

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T16:05:36', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c2ecdda4-2f00-4eaf-8504-161af734a999'	System	06 Oct 2020 21:05:53
User entered 'No (N)'	System	06 Oct 2020 21:05:53

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T16:05:41', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c2ecdda4-2f00-4eaf-8504-161af734a999'	System	06 Oct 2020 21:05:53
User entered 'No (N)'	System	06 Oct 2020 21:05:53

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T16:05:46', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c2ecdda4-2f00-4eaf-8504-161af734a999'	System	06 Oct 2020 21:05:53
User entered 'None (1)'	System	06 Oct 2020 21:05:53

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T16:05:50', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c2ecdda4-2f00-4eaf-8504-161af734a999'	System	06 Oct 2020 21:05:53
User entered '06 Oct 2020 16:05'	System	06 Oct 2020 21:05:53

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '06 Oct 2020 15:59'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '06 Oct 2020 18:29'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	06 Oct 2020 20:42:34
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T19:40:13', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'e75fcf93-d7de-411f-9bc3-7eacdcfd31ba' User entered 'None (1)'	System	07 Oct 2020 00:40:30
	System	07 Oct 2020 00:40:30

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T19:40:17', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'e75fcf93-d7de-411f-9bc3-7eacdcfd31ba' User entered 'No (N)'	System	07 Oct 2020 00:40:30
	System	07 Oct 2020 00:40:30

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T19:40:20', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'e75fcf93-d7de-411f-9bc3-7eacdcfd31ba' User entered 'No (N)'	System	07 Oct 2020 00:40:30
	System	07 Oct 2020 00:40:30

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T19:40:24', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'e75fcf93-d7de-411f-9bc3-7eacdcfd31ba'	System	07 Oct 2020 00:40:30
User entered 'None (1)'	System	07 Oct 2020 00:40:30

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T19:40:27', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'e75fcf93-d7de-411f-9bc3-7eacdcfd31ba' User entered '06 Oct 2020 19:40'	System	07 Oct 2020 00:40:30
	System	07 Oct 2020 00:40:30

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '06 Oct 2020 19:24'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	06 Oct 2020 20:42:34
User entered 'Day 2'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-07T14:52:24', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'eb71869c-3281-4676-8068-bd656a5e54a4'	System	07 Oct 2020 19:52:40
User entered 'None (1)'	System	07 Oct 2020 19:52:40

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-07T14:52:27', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'eb71869c-3281-4676-8068-bd656a5e54a4'	System	07 Oct 2020 19:52:40
User entered 'No (N)'	System	07 Oct 2020 19:52:40

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-07T14:52:30', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'eb71869c-3281-4676-8068-bd656a5e54a4'	System	07 Oct 2020 19:52:40
User entered 'No (N)'	System	07 Oct 2020 19:52:40

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-07T14:52:34', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'eb71869c-3281-4676-8068-bd656a5e54a4'	System	07 Oct 2020 19:52:40
User entered 'None (1)'	System	07 Oct 2020 19:52:40

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-07T14:52:36', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'eb71869c-3281-4676-8068-bd656a5e54a4'	System	07 Oct 2020 19:52:40
User entered '07 Oct 2020 14:52'	System	07 Oct 2020 19:52:40

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	06 Oct 2020 20:42:34
User entered 'Day 3'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-08T12:00:54', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '9d3d942d-ce61-4ad1-9cb1-3a0013e2e97f'	System	08 Oct 2020 17:01:38
User entered 'None (1)'	System	08 Oct 2020 17:01:38

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-08T12:00:57', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '9d3d942d-ce61-4ad1-9cb1-3a0013e2e97f' User entered 'No (N)'	System	08 Oct 2020 17:01:38
	System	08 Oct 2020 17:01:38

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-08T12:00:59', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '9d3d942d-ce61-4ad1-9cb1-3a0013e2e97f' User entered 'No (N)'	System	08 Oct 2020 17:01:38
	System	08 Oct 2020 17:01:38

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-08T12:01:02', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '9d3d942d-ce61-4ad1-9cb1-3a0013e2e97f' User entered 'None (1)'	System	08 Oct 2020 17:01:38
	System	08 Oct 2020 17:01:38

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-08T12:01:04', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '9d3d942d-ce61-4ad1-9cb1-3a0013e2e97f' User entered '08 Oct 2020 12:01'	System	08 Oct 2020 17:01:38
	System	08 Oct 2020 17:01:38

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	06 Oct 2020 20:42:34
User entered 'Day 4'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-09T16:28:50', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '797d3a2c-4e81-4276-83af-4adf9b4f553e' User entered 'None (1)'	System	09 Oct 2020 21:29:06
	System	09 Oct 2020 21:29:06

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-09T16:28:53', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '797d3a2c-4e81-4276-83af-4adf9b4f553e'	System	09 Oct 2020 21:29:06
User entered 'No (N)'	System	09 Oct 2020 21:29:06

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-09T16:28:56', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '797d3a2c-4e81-4276-83af-4adf9b4f553e' User entered 'No (N)'	System	09 Oct 2020 21:29:06
	System	09 Oct 2020 21:29:06

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-09T16:28:59', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '797d3a2c-4e81-4276-83af-4adf9b4f553e' User entered 'None (1)'	System	09 Oct 2020 21:29:06
	System	09 Oct 2020 21:29:06

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-09T16:29:02', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '797d3a2c-4e81-4276-83af-4adf9b4f553e' User entered '09 Oct 2020 16:29'	System	09 Oct 2020 21:29:06
	System	09 Oct 2020 21:29:06

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	06 Oct 2020 20:42:34
User entered 'Day 5'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-10T13:22:39', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '50f8b1e1-d913-488e-bf51-918c665dd845'	System	10 Oct 2020 18:22:55
User entered 'None (1)'	System	10 Oct 2020 18:22:55

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-10T13:22:44', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '50f8b1e1-d913-488e-bf51-918c665dd845'	System	10 Oct 2020 18:22:55
User entered 'No (N)'	System	10 Oct 2020 18:22:55

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-10T13:22:47', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '50f8b1e1-d913-488e-bf51-918c665dd845'	System	10 Oct 2020 18:22:55
User entered 'No (N)'	System	10 Oct 2020 18:22:55

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-10T13:22:49', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '50f8b1e1-d913-488e-bf51-918c665dd845'	System	10 Oct 2020 18:22:55
User entered 'None (1)'	System	10 Oct 2020 18:22:55

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-10T13:22:52', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '50f8b1e1-d913-488e-bf51-918c665dd845' User entered '10 Oct 2020 13:22'	System	10 Oct 2020 18:22:55
	System	10 Oct 2020 18:22:55

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	06 Oct 2020 20:42:34
User entered 'Day 6'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-11T13:15:08', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b51a5a9e-e6c1-4c12-a22f-991e73dd5886'	System	11 Oct 2020 18:15:23
User entered 'None (1)'	System	11 Oct 2020 18:15:23

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-11T13:15:11', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b51a5a9e-e6c1-4c12-a22f-991e73dd5886'	System	11 Oct 2020 18:15:23
User entered 'No (N)'	System	11 Oct 2020 18:15:23

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-11T13:15:14', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b51a5a9e-e6c1-4c12-a22f-991e73dd5886'	System	11 Oct 2020 18:15:23
User entered 'No (N)'	System	11 Oct 2020 18:15:23

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-11T13:15:16', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b51a5a9e-e6c1-4c12-a22f-991e73dd5886'	System	11 Oct 2020 18:15:23
User entered 'None (1)'	System	11 Oct 2020 18:15:23

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-11T13:15:19', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b51a5a9e-e6c1-4c12-a22f-991e73dd5886' User entered '11 Oct 2020 13:15'	System	11 Oct 2020 18:15:23
	System	11 Oct 2020 18:15:23

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	06 Oct 2020 20:42:34
User entered 'Day 7'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-13T06:19:44', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '2bb4a495-1e3e-4e77-9b1a-9c501f6cfd20'	System	13 Oct 2020 11:19:56
User entered 'None (1)'	System	13 Oct 2020 11:19:56

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-13T06:19:47', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '2bb4a495-1e3e-4e77-9b1a-9c501f6cfd20'	System	13 Oct 2020 11:19:56
User entered 'No (N)'	System	13 Oct 2020 11:19:56

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-13T06:19:49', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '2bb4a495-1e3e-4e77-9b1a-9c501f6cfd20'	System	13 Oct 2020 11:19:56
User entered 'No (N)'	System	13 Oct 2020 11:19:56

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-13T06:19:51', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '2bb4a495-1e3e-4e77-9b1a-9c501f6cfd20'	System	13 Oct 2020 11:19:56
User entered 'None (1)'	System	13 Oct 2020 11:19:56

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-13T06:19:54', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '2bb4a495-1e3e-4e77-9b1a-9c501f6cfd20' User entered '13 Oct 2020 06:19'	System	13 Oct 2020 11:19:56
	System	13 Oct 2020 11:19:56

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:37
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	06 Oct 2020 20:42:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T16:05:55', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '12fce3d7-72a9-4920-b607-0a0f0ca48da0' User entered 'None (0)'	System	06 Oct 2020 21:06:19
	System	06 Oct 2020 21:06:19

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T16:05:58', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '12fce3d7-72a9-4920-b607-0a0f0ca48da0' User entered 'None (0)'	System	06 Oct 2020 21:06:19
	System	06 Oct 2020 21:06:19

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T16:06:01', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '12fce3d7-72a9-4920-b607-0a0f0ca48da0' User entered 'None (0)'	System	06 Oct 2020 21:06:19
	System	06 Oct 2020 21:06:19

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T16:06:05', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '12fce3d7-72a9-4920-b607-0a0f0ca48da0' User entered 'None (0)'	System	06 Oct 2020 21:06:19
	System	06 Oct 2020 21:06:19

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T16:06:08', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '12fce3d7-72a9-4920-b607-0a0f0ca48da0' User entered 'None (0)'	System	06 Oct 2020 21:06:19
	System	06 Oct 2020 21:06:19

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T16:06:11', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '12fce3d7-72a9-4920-b607-0a0f0ca48da0' User entered 'None (0)'	System	06 Oct 2020 21:06:19
	System	06 Oct 2020 21:06:19

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

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)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T16:06:14', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '12fce3d7-72a9-4920-b607-0a0f0ca48da0'	System	06 Oct 2020 21:06:19
User entered 'No (N)'	System	06 Oct 2020 21:06:19

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T16:06:18', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '12fce3d7-72a9-4920-b607-0a0f0ca48da0' User entered '06 Oct 2020 16:06'	System	06 Oct 2020 21:06:19
	System	06 Oct 2020 21:06:19

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '06 Oct 2020 15:59'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '06 Oct 2020 18:29'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	06 Oct 2020 20:42:34
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T19:40:34', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '7f0b8840-862a-403b-a9bf-a4b6d16abe59' User entered 'None (0)'	System	07 Oct 2020 00:41:01
	System	07 Oct 2020 00:41:01

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T19:40:38', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '7f0b8840-862a-403b-a9bf-a4b6d16abe59' User entered 'None (0)'	System	07 Oct 2020 00:41:01
	System	07 Oct 2020 00:41:01

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T19:40:41', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '7f0b8840-862a-403b-a9bf-a4b6d16abe59'	System	07 Oct 2020 00:41:01
User entered 'None (0)'	System	07 Oct 2020 00:41:01

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T19:40:45', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '7f0b8840-862a-403b-a9bf-a4b6d16abe59' User entered 'None (0)'	System	07 Oct 2020 00:41:01
	System	07 Oct 2020 00:41:01

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T19:40:48', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '7f0b8840-862a-403b-a9bf-a4b6d16abe59'	System	07 Oct 2020 00:41:01
User entered 'None (0)'	System	07 Oct 2020 00:41:01

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T19:40:52', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '7f0b8840-862a-403b-a9bf-a4b6d16abe59' User entered 'None (0)'	System	07 Oct 2020 00:41:01
	System	07 Oct 2020 00:41:01

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

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)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T19:40:55', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '7f0b8840-862a-403b-a9bf-a4b6d16abe59'	System	07 Oct 2020 00:41:01
User entered 'No (N)'	System	07 Oct 2020 00:41:01

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-06T19:40:58', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '7f0b8840-862a-403b-a9bf-a4b6d16abe59' User entered '06 Oct 2020 19:40'	System	07 Oct 2020 00:41:01
	System	07 Oct 2020 00:41:01

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '06 Oct 2020 19:24'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	06 Oct 2020 20:42:34
User entered 'Day 2'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-07T14:52:41', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '22fe512c-8c7d-4e9c-ae26-83ad73290f9e' User entered 'None (0)'	System	07 Oct 2020 19:53:18
	System	07 Oct 2020 19:53:18

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-07T14:52:51', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '22fe512c-8c7d-4e9c-ae26-83ad73290f9e'	System	07 Oct 2020 19:53:18
User entered 'No interference with activity (1)'	System	07 Oct 2020 19:53:18

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-07T14:52:57', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '22fe512c-8c7d-4e9c-ae26-83ad73290f9e' User entered 'None (0)'	System	07 Oct 2020 19:53:18
	System	07 Oct 2020 19:53:18

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-07T14:53:03', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '22fe512c-8c7d-4e9c-ae26-83ad73290f9e'	System	07 Oct 2020 19:53:18
User entered 'No interference with activity (1)'	System	07 Oct 2020 19:53:18

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-07T14:53:06', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '22fe512c-8c7d-4e9c-ae26-83ad73290f9e' User entered 'None (0)'	System	07 Oct 2020 19:53:18
	System	07 Oct 2020 19:53:18

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-07T14:53:09', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '22fe512c-8c7d-4e9c-ae26-83ad73290f9e' User entered 'None (0)'	System	07 Oct 2020 19:53:18
	System	07 Oct 2020 19:53:18

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:34

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)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-07T14:53:12', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '22fe512c-8c7d-4e9c-ae26-83ad73290f9e'	System	07 Oct 2020 19:53:18
User entered 'No (N)'	System	07 Oct 2020 19:53:18

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-07T14:53:16', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '22fe512c-8c7d-4e9c-ae26-83ad73290f9e' User entered '07 Oct 2020 14:53'	System	07 Oct 2020 19:53:18
	System	07 Oct 2020 19:53:18

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	06 Oct 2020 20:42:34
User entered 'Day 3'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-08T12:01:09', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '26ed6dba-f179-4b65-a382-c8477ac33609' User entered 'None (0)'	System	08 Oct 2020 17:02:09
	System	08 Oct 2020 17:02:09

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-08T12:01:11', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '26ed6dba-f179-4b65-a382-c8477ac33609' User entered 'None (0)'	System	08 Oct 2020 17:02:09
	System	08 Oct 2020 17:02:09

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-08T12:01:13', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '26ed6dba-f179-4b65-a382-c8477ac33609' User entered 'None (0)'	System	08 Oct 2020 17:02:09
	System	08 Oct 2020 17:02:09

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-08T12:01:14', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '26ed6dba-f179-4b65-a382-c8477ac33609' User entered 'None (0)'	System	08 Oct 2020 17:02:09
	System	08 Oct 2020 17:02:09

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-08T12:01:16', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '26ed6dba-f179-4b65-a382-c8477ac33609' User entered 'None (0)'	System	08 Oct 2020 17:02:09
	System	08 Oct 2020 17:02:09

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-08T12:01:18', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '26ed6dba-f179-4b65-a382-c8477ac33609' User entered 'None (0)'	System	08 Oct 2020 17:02:09
	System	08 Oct 2020 17:02:09

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:34

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)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-08T12:01:22', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '26ed6dba-f179-4b65-a382-c8477ac33609'	System	08 Oct 2020 17:02:09
User entered 'No (N)'	System	08 Oct 2020 17:02:09

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-08T12:01:25', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '26ed6dba-f179-4b65-a382-c8477ac33609' User entered '08 Oct 2020 12:01'	System	08 Oct 2020 17:02:09
	System	08 Oct 2020 17:02:09

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	06 Oct 2020 20:42:34
User entered 'Day 4'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-09T16:29:07', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '4c944f5d-4f40-4990-ac54-29e6505b766e' User entered 'None (0)'	System	09 Oct 2020 21:29:38
	System	09 Oct 2020 21:29:38

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-09T16:29:09', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '4c944f5d-4f40-4990-ac54-29e6505b766e' User entered 'None (0)'	System	09 Oct 2020 21:29:38
	System	09 Oct 2020 21:29:38

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-09T16:29:12', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '4c944f5d-4f40-4990-ac54-29e6505b766e' User entered 'None (0)'	System	09 Oct 2020 21:29:38
	System	09 Oct 2020 21:29:38

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-09T16:29:22', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '4c944f5d-4f40-4990-ac54-29e6505b766e' User entered 'None (0)'	System	09 Oct 2020 21:29:38
	System	09 Oct 2020 21:29:38

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-09T16:29:24', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '4c944f5d-4f40-4990-ac54-29e6505b766e' User entered 'None (0)'	System	09 Oct 2020 21:29:38
	System	09 Oct 2020 21:29:38

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-09T16:29:27', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '4c944f5d-4f40-4990-ac54-29e6505b766e' User entered 'None (0)'	System	09 Oct 2020 21:29:38
	System	09 Oct 2020 21:29:38

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:34

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)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-09T16:29:30', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '4c944f5d-4f40-4990-ac54-29e6505b766e' User entered 'No (N)'	System	09 Oct 2020 21:29:38
	System	09 Oct 2020 21:29:38

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-09T16:29:35', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '4c944f5d-4f40-4990-ac54-29e6505b766e' User entered '09 Oct 2020 16:29'	System	09 Oct 2020 21:29:38
	System	09 Oct 2020 21:29:38

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	06 Oct 2020 20:42:34
User entered 'Day 5'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-10T13:22:57', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '60900fb9-7306-4930-b1b2-8a5452bfcff8'	System	10 Oct 2020 18:23:18
User entered 'None (0)'	System	10 Oct 2020 18:23:18

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-10T13:22:59', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '60900fb9-7306-4930-b1b2-8a5452bfcff8'	System	10 Oct 2020 18:23:18
User entered 'None (0)'	System	10 Oct 2020 18:23:18

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-10T13:23:01', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '60900fb9-7306-4930-b1b2-8a5452bfcff8'	System	10 Oct 2020 18:23:18
User entered 'None (0)'	System	10 Oct 2020 18:23:18

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-10T13:23:05', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '60900fb9-7306-4930-b1b2-8a5452bfcff8'	System	10 Oct 2020 18:23:18
User entered 'None (0)'	System	10 Oct 2020 18:23:18

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-10T13:23:07', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '60900fb9-7306-4930-b1b2-8a5452bfcff8'	System	10 Oct 2020 18:23:18
User entered 'None (0)'	System	10 Oct 2020 18:23:18

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-10T13:23:09', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '60900fb9-7306-4930-b1b2-8a5452bfcff8'	System	10 Oct 2020 18:23:18
User entered 'None (0)'	System	10 Oct 2020 18:23:18

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:34

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)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-10T13:23:13', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '60900fb9-7306-4930-b1b2-8a5452bfcff8'	System	10 Oct 2020 18:23:18
User entered 'No (N)'	System	10 Oct 2020 18:23:18

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-10T13:23:15', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '60900fb9-7306-4930-b1b2-8a5452bfcff8' User entered '10 Oct 2020 13:23'	System	10 Oct 2020 18:23:18
	System	10 Oct 2020 18:23:18

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	06 Oct 2020 20:42:34
User entered 'Day 6'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-11T13:15:25', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '5b8c7e1b-babc-4bda-a134-9409ce421982' User entered 'None (0)'	System	11 Oct 2020 18:15:47
	System	11 Oct 2020 18:15:47

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-11T13:15:28', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '5b8c7e1b-babc-4bda-a134-9409ce421982'	System	11 Oct 2020 18:15:47
User entered 'None (0)'	System	11 Oct 2020 18:15:47

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-11T13:15:30', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '5b8c7e1b-babc-4bda-a134-9409ce421982'	System	11 Oct 2020 18:15:47
User entered 'None (0)'	System	11 Oct 2020 18:15:47

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-11T13:15:32', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '5b8c7e1b-babc-4bda-a134-9409ce421982' User entered 'None (0)'	System	11 Oct 2020 18:15:47
	System	11 Oct 2020 18:15:47

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-11T13:15:35', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '5b8c7e1b-babc-4bda-a134-9409ce421982'	System	11 Oct 2020 18:15:47
User entered 'None (0)'	System	11 Oct 2020 18:15:47

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-11T13:15:37', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '5b8c7e1b-babc-4bda-a134-9409ce421982'	System	11 Oct 2020 18:15:47
User entered 'None (0)'	System	11 Oct 2020 18:15:47

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:34

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)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-11T13:15:41', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '5b8c7e1b-babc-4bda-a134-9409ce421982'	System	11 Oct 2020 18:15:47
User entered 'No (N)'	System	11 Oct 2020 18:15:47

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-11T13:15:44', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '5b8c7e1b-babc-4bda-a134-9409ce421982'	System	11 Oct 2020 18:15:47
User entered '11 Oct 2020 13:15'	System	11 Oct 2020 18:15:47

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	06 Oct 2020 20:42:34
User entered 'Day 7'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-13T06:19:58', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '115480ab-18a7-41a8-98b3-90d9e658ab1e' User entered 'None (0)'	System	13 Oct 2020 11:20:15
	System	13 Oct 2020 11:20:15

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-13T06:19:59', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '115480ab-18a7-41a8-98b3-90d9e658ab1e' User entered 'None (0)'	System	13 Oct 2020 11:20:15
	System	13 Oct 2020 11:20:15

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-13T06:20:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '115480ab-18a7-41a8-98b3-90d9e658ab1e' User entered 'None (0)'	System	13 Oct 2020 11:20:15
	System	13 Oct 2020 11:20:15

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-13T06:20:03', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '115480ab-18a7-41a8-98b3-90d9e658ab1e' User entered 'None (0)'	System	13 Oct 2020 11:20:15
	System	13 Oct 2020 11:20:15

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-13T06:20:04', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '115480ab-18a7-41a8-98b3-90d9e658ab1e' User entered 'None (0)'	System	13 Oct 2020 11:20:15
	System	13 Oct 2020 11:20:15

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-13T06:20:06', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '115480ab-18a7-41a8-98b3-90d9e658ab1e' User entered 'None (0)'	System	13 Oct 2020 11:20:15
	System	13 Oct 2020 11:20:15

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:34

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)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-13T06:20:10', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '115480ab-18a7-41a8-98b3-90d9e658ab1e'	System	13 Oct 2020 11:20:15
User entered 'No (N)'	System	13 Oct 2020 11:20:15

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-10-13T06:20:12', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '115480ab-18a7-41a8-98b3-90d9e658ab1e' User entered '13 Oct 2020 06:20'	System	13 Oct 2020 11:20:15
	System	13 Oct 2020 11:20:15

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 20:42:34

US3002259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:27:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 20:42:34

US3002259

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:32:06

US3002259

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:32:06

US3002259

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:32:06

US3002259

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:32:06

US3002259

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:32:09

US3002259

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'I'	System	21 Oct 2020 16:32:09

US3002259

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:32:19

US3002259

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '20 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:32:19

US3002259

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:32:19

US3002259

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 16:32:19

US3002259

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:32:22

US3002259

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'I'	System	21 Oct 2020 16:32:22

US3002259

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:43:12

US3002259

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:43:12

US3002259

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:43:12

US3002259

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:43:12

US3002259

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:43:15

US3002259

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'I'	System	02 Nov 2020 22:43:15

US3002259

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:43:34

US3002259

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '02 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:43:34

US3002259

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:43:34

US3002259

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'VISIT3'	System	02 Nov 2020 22:43:34

US3002259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:43:51

US3002259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '02 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:43:51

US3002259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '14:58'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:43:51

US3002259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered '02 Nov 2020 14:58'	System	02 Nov 2020 22:43:51

US3002259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '36.7' C	(b) (4), (b) (6)	02 Nov 2020 22:43:51

US3002259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:43:51

US3002259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:43:51

US3002259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '72'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:43:51

US3002259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'bpm'	System	02 Nov 2020 22:43:51

US3002259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '14'	(b) (4), (b) (6)	02 Nov 2020 22:43:51

US3002259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'breaths/min'	System	02 Nov 2020 22:43:51

US3002259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '135'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:43:51

US3002259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'mmHg'	System	02 Nov 2020 22:43:51

US3002259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '78'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:43:51

US3002259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'mmHg'	System	02 Nov 2020 22:43:51

US3002259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04

US3002259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04

US3002259

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:44:01

US3002259

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '02 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:44:01

US3002259

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:44:12

US3002259

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '02 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:44:12

US3002259

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:34

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '15:18'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:44:12

US3002259

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered '02 Nov 2020 15:18'	System	02 Nov 2020 22:44:12

US3002259

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:44:15

US3002259

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'I'	System	02 Nov 2020 22:44:15

US3002259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:28:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered 'Day 64'	System	08 Sep 2020 16:57:38

US3002259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:28:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-11-08T10:54:37', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '359b626d-28bc-46d5-893a-e794675c518f' User entered 'No (N)'	System	08 Nov 2020 16:54:48
	System	08 Nov 2020 16:54:48

US3002259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Have you been exposed to someone with 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)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:28:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-11-08T10:54:26', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '359b626d-28bc-46d5-893a-e794675c518f'	System	08 Nov 2020 16:54:48
User entered 'No (N)'	System	08 Nov 2020 16:54:48

US3002259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:28:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-11-08T10:54:43', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '359b626d-28bc-46d5-893a-e794675c518f' User entered '08 Nov 2020 10:54:43'	System	08 Nov 2020 16:54:48
	System	08 Nov 2020 16:54:48

US3002259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:28:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered '08 Nov 2020 00:01'	System	08 Sep 2020 16:57:38

US3002259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:28:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered '12 Nov 2020 23:59'	System	08 Sep 2020 16:57:38

US3002259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:28:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered 'Day 71'	System	08 Sep 2020 16:57:38

US3002259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

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)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:28:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-11-15T09:14:42', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'fe9fab94-a5b2-4b2f-b7ba-762ea54fb717'	System	15 Nov 2020 15:14:52
User entered 'No (N)'	System	15 Nov 2020 15:14:52

US3002259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Have you been exposed to someone with 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)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:28:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-11-15T09:14:37', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'fe9fab94-a5b2-4b2f-b7ba-762ea54fb717'	System	15 Nov 2020 15:14:52
User entered 'No (N)'	System	15 Nov 2020 15:14:52

US3002259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:28:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-11-15T09:14:47', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'fe9fab94-a5b2-4b2f-b7ba-762ea54fb717'	System	15 Nov 2020 15:14:52
User entered '15 Nov 2020 09:14:47'	System	15 Nov 2020 15:14:52

US3002259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:28:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered '15 Nov 2020 00:01'	System	08 Sep 2020 16:57:38

US3002259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:38:22
Data hard unlocked.	(b) (4), (b) (6)	26 Feb 2021 22:28:42
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:01:35
Data entry locked.	System	08 Sep 2020 16:57:38
User entered '19 Nov 2020 23:59'	System	08 Sep 2020 16:57:38

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-11-22T09:51:27', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '702cb3d8-b8eb-4c66-af83-bbdf65b99cc4' User entered 'No (N)'	System	22 Nov 2020 15:52:22
	System	22 Nov 2020 15:52:22

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Have you been exposed to someone with 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-11-22T09:51:35', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '702cb3d8-b8eb-4c66-af83-bbdf65b99cc4'	System	22 Nov 2020 15:52:22
User entered 'Yes (Y)'	System	22 Nov 2020 15:52:22

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-11-22T09:51:58', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '702cb3d8-b8eb-4c66-af83-bbdf65b99cc4'	System	22 Nov 2020 15:52:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Nov 2020 15:52:22

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-11-22T09:52:12', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '702cb3d8-b8eb-4c66-af83-bbdf65b99cc4' User entered '22 Nov 2020 09:52:12'	System	22 Nov 2020 15:52:22
	System	22 Nov 2020 15:52:22

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-11-26T09:15:48', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '84c7366b-3b42-4815-98d4-4e7b45ab9ef4' User entered 'No (N)'	System	26 Nov 2020 15:16:31
	System	26 Nov 2020 15:16:31

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Have you been exposed to someone with 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-11-26T09:15:59', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '84c7366b-3b42-4815-98d4-4e7b45ab9ef4' User entered 'Yes (Y)'	System	26 Nov 2020 15:16:31
	System	26 Nov 2020 15:16:31

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-11-26T09:16:12', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '84c7366b-3b42-4815-98d4-4e7b45ab9ef4'	System	26 Nov 2020 15:16:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Nov 2020 15:16:31

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-11-26T09:16:22', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '84c7366b-3b42-4815-98d4-4e7b45ab9ef4' User entered '26 Nov 2020 09:16:22'	System	26 Nov 2020 15:16:31
	System	26 Nov 2020 15:16:31

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-03T09:11:26', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c8af5548-fa72-4a64-ac13-3570667cb49d'	System	03 Dec 2020 15:15:49
User entered 'Yes (Y)'	System	03 Dec 2020 15:15:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Have you been exposed to someone with 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-03T09:12:25', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c8af5548-fa72-4a64-ac13-3570667cb49d'	System	03 Dec 2020 15:15:49
User entered 'Yes (Y)'	System	03 Dec 2020 15:15:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-03T09:12:40', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c8af5548-fa72-4a64-ac13-3570667cb49d'	System	03 Dec 2020 15:15:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Dec 2020 15:15:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Have you experienced any new COVID-19 disease symptoms 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-03T09:13:08', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c8af5548-fa72-4a64-ac13-3570667cb49d'	System	03 Dec 2020 15:15:49
User entered 'Yes (Y)'	System	03 Dec 2020 15:15:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-03T09:14:21', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c8af5548-fa72-4a64-ac13-3570667cb49d' User entered '0'	System	03 Dec 2020 15:15:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-03T09:14:21', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c8af5548-fa72-4a64-ac13-3570667cb49d'	System	03 Dec 2020 15:15:49
User entered '1'	System	03 Dec 2020 15:15:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-03T09:14:21', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c8af5548-fa72-4a64-ac13-3570667cb49d' User entered '0'	System	03 Dec 2020 15:15:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-03T09:14:21', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c8af5548-fa72-4a64-ac13-3570667cb49d' User entered '0'	System	03 Dec 2020 15:15:49
	System	03 Dec 2020 15:15:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-03T09:14:21', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c8af5548-fa72-4a64-ac13-3570667cb49d' User entered '0'	System	03 Dec 2020 15:15:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-03T09:14:21', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c8af5548-fa72-4a64-ac13-3570667cb49d' User entered '1'	System	03 Dec 2020 15:15:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-03T09:14:21', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c8af5548-fa72-4a64-ac13-3570667cb49d' User entered '0'	System	03 Dec 2020 15:15:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-03T09:14:21', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c8af5548-fa72-4a64-ac13-3570667cb49d' User entered '0'	System	03 Dec 2020 15:15:49
	System	03 Dec 2020 15:15:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-03T09:14:21', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c8af5548-fa72-4a64-ac13-3570667cb49d' User entered '0'	System	03 Dec 2020 15:15:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-03T09:14:21', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c8af5548-fa72-4a64-ac13-3570667cb49d' User entered '0'	System	03 Dec 2020 15:15:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-03T09:14:21', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c8af5548-fa72-4a64-ac13-3570667cb49d' User entered '0'	System	03 Dec 2020 15:15:49
	System	03 Dec 2020 15:15:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-03T09:14:21', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c8af5548-fa72-4a64-ac13-3570667cb49d' User entered '0'	System	03 Dec 2020 15:15:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-03T09:14:21', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c8af5548-fa72-4a64-ac13-3570667cb49d' User entered '0'	System	03 Dec 2020 15:15:49
	System	03 Dec 2020 15:15:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-03T09:14:21', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c8af5548-fa72-4a64-ac13-3570667cb49d' User entered '1'	System	03 Dec 2020 15:15:49
	System	03 Dec 2020 15:15:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-03T09:14:21', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c8af5548-fa72-4a64-ac13-3570667cb49d' User entered '0'	System	03 Dec 2020 15:15:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-03T09:14:21', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c8af5548-fa72-4a64-ac13-3570667cb49d' User entered '0'	System	03 Dec 2020 15:15:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-03T09:14:21', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c8af5548-fa72-4a64-ac13-3570667cb49d'	System	03 Dec 2020 15:15:49
User entered '1'	System	03 Dec 2020 15:15:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-03T09:14:45', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c8af5548-fa72-4a64-ac13-3570667cb49d'	System	03 Dec 2020 15:15:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Dec 2020 15:15:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Have you had to contact a healthcare provider 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-03T09:14:58', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c8af5548-fa72-4a64-ac13-3570667cb49d'	System	03 Dec 2020 15:15:49
User entered 'Yes (Y)'	System	03 Dec 2020 15:15:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-03T09:15:14', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c8af5548-fa72-4a64-ac13-3570667cb49d'	System	03 Dec 2020 15:15:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Dec 2020 15:15:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-03T09:15:40', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'c8af5548-fa72-4a64-ac13-3570667cb49d' User entered '03 Dec 2020 09:15:40'	System	03 Dec 2020 15:15:49
	System	03 Dec 2020 15:15:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-12T13:09:59', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'd6f484af-e097-4075-904c-d17450d88d17' User entered 'No (N)'	System	12 Dec 2020 19:11:13
	System	12 Dec 2020 19:11:13

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Have you been exposed to someone with 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-12T13:10:56', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'd6f484af-e097-4075-904c-d17450d88d17'	System	12 Dec 2020 19:11:13
User entered 'Yes (Y)'	System	12 Dec 2020 19:11:13

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-12T13:10:06', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'd6f484af-e097-4075-904c-d17450d88d17'	System	12 Dec 2020 19:11:13
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Dec 2020 19:11:13

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-12T13:11:04', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'd6f484af-e097-4075-904c-d17450d88d17' User entered '12 Dec 2020 13:11:04'	System	12 Dec 2020 19:11:13
	System	12 Dec 2020 19:11:13

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-19T12:42:54', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '5a8af085-9b8e-49df-87db-64dae1b7cd4e'	System	19 Dec 2020 18:43:08
User entered 'No (N)'	System	19 Dec 2020 18:43:08

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Have you been exposed to someone with 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-19T12:43:01', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '5a8af085-9b8e-49df-87db-64dae1b7cd4e'	System	19 Dec 2020 18:43:08
User entered 'No (N)'	System	19 Dec 2020 18:43:08

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-19T12:43:06', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '5a8af085-9b8e-49df-87db-64dae1b7cd4e' User entered '19 Dec 2020 12:43:06'	System	19 Dec 2020 18:43:08
	System	19 Dec 2020 18:43:08

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-25T07:52:58', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '5473adac-7e3e-4962-8303-e9da214969c8' User entered 'No (N)'	System	25 Dec 2020 13:53:12
	System	25 Dec 2020 13:53:12

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Have you been exposed to someone with 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-25T07:53:06', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '5473adac-7e3e-4962-8303-e9da214969c8' User entered 'No (N)'	System	25 Dec 2020 13:53:12
	System	25 Dec 2020 13:53:12

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2020-12-25T07:53:10', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '5473adac-7e3e-4962-8303-e9da214969c8' User entered '25 Dec 2020 07:53:10'	System	25 Dec 2020 13:53:12
	System	25 Dec 2020 13:53:12

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-01-02T12:01:15', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '237b065b-3f26-4f79-bbe8-adfd173a2c3a'	System	02 Jan 2021 18:01:27
User entered 'No (N)'	System	02 Jan 2021 18:01:27

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Have you been exposed to someone with 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-01-02T12:01:19', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '237b065b-3f26-4f79-bbe8-adfd173a2c3a' User entered 'No (N)'	System	02 Jan 2021 18:01:27
	System	02 Jan 2021 18:01:27

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-01-02T12:01:24', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '237b065b-3f26-4f79-bbe8-adfd173a2c3a' User entered '02 Jan 2021 12:01:24'	System	02 Jan 2021 18:01:27
	System	02 Jan 2021 18:01:27

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-01-07T11:05:03', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '82df4d00-0016-4af8-b005-accc62cdaa32'	System	07 Jan 2021 17:05:38
User entered 'Yes (Y)'	System	07 Jan 2021 17:05:38

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Have you been exposed to someone with 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-01-07T11:05:07', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '82df4d00-0016-4af8-b005-acc62cdaa32'	System	07 Jan 2021 17:05:38
User entered 'No (N)'	System	07 Jan 2021 17:05:38

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Have you experienced any new COVID-19 disease symptoms 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-01-07T11:05:11', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '82df4d00-0016-4af8-b005-accc62cdaa32'	System	07 Jan 2021 17:05:38
User entered 'No (N)'	System	07 Jan 2021 17:05:38

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Have you had to contact a healthcare provider 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-01-07T11:05:30', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '82df4d00-0016-4af8-b005-accc62cdaa32'	System	07 Jan 2021 17:05:38
User entered 'No (N)'	System	07 Jan 2021 17:05:38

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-01-07T11:05:37', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '82df4d00-0016-4af8-b005-acc62cdaa32' User entered '07 Jan 2021 11:05:37'	System	07 Jan 2021 17:05:38
	System	07 Jan 2021 17:05:38

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-01-16T12:46:39', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'd571d79a-0a84-4384-bf6d-52427162d7a0'	System	16 Jan 2021 18:46:49
User entered 'No (N)'	System	16 Jan 2021 18:46:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Have you been exposed to someone with 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-01-16T12:46:43', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'd571d79a-0a84-4384-bf6d-52427162d7a0'	System	16 Jan 2021 18:46:49
User entered 'No (N)'	System	16 Jan 2021 18:46:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-01-16T12:46:47', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'd571d79a-0a84-4384-bf6d-52427162d7a0' User entered '16 Jan 2021 12:46:47'	System	16 Jan 2021 18:46:49
	System	16 Jan 2021 18:46:49

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-01-21T08:04:45', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '49633d4b-fea9-40c0-b9cd-180a35cdaf53' User entered 'No (N)'	System	21 Jan 2021 14:04:57
	System	21 Jan 2021 14:04:57

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Have you been exposed to someone with 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-01-21T08:04:49', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '49633d4b-fea9-40c0-b9cd-180a35cdaf53'	System	21 Jan 2021 14:04:57
User entered 'No (N)'	System	21 Jan 2021 14:04:57

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-01-21T08:04:53', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '49633d4b-fea9-40c0-b9cd-180a35cdaf53' User entered '21 Jan 2021 08:04:53'	System	21 Jan 2021 14:04:57
	System	21 Jan 2021 14:04:57

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-01-28T07:59:16', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '667257b1-41c2-44a2-a3b4-7ccd85ef1091' User entered 'No (N)'	System	28 Jan 2021 13:59:26
	System	28 Jan 2021 13:59:26

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Have you been exposed to someone with 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-01-28T07:59:20', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '667257b1-41c2-44a2-a3b4-7ccd85ef1091'	System	28 Jan 2021 13:59:26
User entered 'No (N)'	System	28 Jan 2021 13:59:26

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-01-28T07:59:24', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '667257b1-41c2-44a2-a3b4-7ccd85ef1091' User entered '28 Jan 2021 07:59:24'	System	28 Jan 2021 13:59:26
	System	28 Jan 2021 13:59:26

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-02-04T08:13:19', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '90dfa97b-b951-4df8-877b-61fea56f96cd' User entered 'No (N)'	System	04 Feb 2021 14:13:33
	System	04 Feb 2021 14:13:33

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Have you been exposed to someone with 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-02-04T08:13:23', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '90dfa97b-b951-4df8-877b-61fea56f96cd' User entered 'No (N)'	System	04 Feb 2021 14:13:33
	System	04 Feb 2021 14:13:33

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-02-04T08:13:28', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '90dfa97b-b951-4df8-877b-61fea56f96cd' User entered '04 Feb 2021 08:13:28'	System	04 Feb 2021 14:13:33
	System	04 Feb 2021 14:13:33

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-02-11T09:39:23', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'f62dcef2-2a26-4876-869a-90bd85260f1b' User entered 'No (N)'	System	11 Feb 2021 15:39:29
	System	11 Feb 2021 15:39:29

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Have you been exposed to someone with 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-02-11T09:39:04', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'f62dcef2-2a26-4876-869a-90bd85260f1b' User entered 'No (N)'	System	11 Feb 2021 15:39:29
	System	11 Feb 2021 15:39:29

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-02-11T09:39:26', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'f62dcef2-2a26-4876-869a-90bd85260f1b' User entered '11 Feb 2021 09:39:26'	System	11 Feb 2021 15:39:29
	System	11 Feb 2021 15:39:29

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-02-18T11:12:19', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '7e5e5059-7069-424c-bffe-0c7b3384c6fc' User entered 'No (N)'	System	18 Feb 2021 17:17:08
	System	18 Feb 2021 17:17:08

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Have you been exposed to someone with 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-02-18T11:12:22', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '7e5e5059-7069-424c-bffe-0c7b3384c6fc' User entered 'No (N)'	System	18 Feb 2021 17:17:08
	System	18 Feb 2021 17:17:08

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-02-18T11:12:26', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '7e5e5059-7069-424c-bffe-0c7b3384c6fc' User entered '18 Feb 2021 11:12:26'	System	18 Feb 2021 17:17:08
	System	18 Feb 2021 17:17:08

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-02-25T08:32:26-06:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'eb2ce319-bbf1-461a-b63a-24f5296a4adf' User entered 'No (N)'	System	25 Feb 2021 14:32:42

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Have you been exposed to someone with 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-02-25T08:32:35-06:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'eb2ce319-bbf1-461a-b63a-24f5296a4adf' User entered 'No (N)'	System	25 Feb 2021 14:32:42

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-02-25T08:32:40-06:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'eb2ce319-bbf1-461a-b63a-24f5296a4adf' User entered '25 Feb 2021 14:32:40'	System	25 Feb 2021 14:32:42

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-03-05T18:27:22-06:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '3972ad96-942c-4278-a788-6cf68fa52ccd'	System	06 Mar 2021 00:27:58
User entered 'No (N)'	System	06 Mar 2021 00:27:58

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Have you been exposed to someone with 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-03-05T18:27:25-06:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '3972ad96-942c-4278-a788-6cf68fa52ccd'	System	06 Mar 2021 00:27:58
User entered 'No (N)'	System	06 Mar 2021 00:27:58

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-03-05T18:27:29-06:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '3972ad96-942c-4278-a788-6cf68fa52ccd' User entered '05 Mar 2021 18:27:29'	System	06 Mar 2021 00:27:58
	System	06 Mar 2021 00:27:58

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-03-13T15:49:14-06:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '1a4ec764-77a7-4cb8-b82b-1bd4f5965a5a'	System	13 Mar 2021 21:49:27
User entered 'No (N)'	System	13 Mar 2021 21:49:27

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Have you been exposed to someone with 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-03-13T15:49:18-06:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '1a4ec764-77a7-4cb8-b82b-1bd4f5965a5a' User entered 'No (N)'	System	13 Mar 2021 21:49:27

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-03-13T15:49:21-06:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '1a4ec764-77a7-4cb8-b82b-1bd4f5965a5a' User entered '13 Mar 2021 15:49:21'	System	13 Mar 2021 21:49:27
	System	13 Mar 2021 21:49:27

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-03-18T09:38:54-05:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '1c077a08-13e5-40ef-a32b-7945fae1d04c'	System	18 Mar 2021 14:39:10
User entered 'No (N)'	System	18 Mar 2021 14:39:10

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Have you been exposed to someone with 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-03-18T09:38:58-05:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '1c077a08-13e5-40ef-a32b-7945fae1d04c'	System	18 Mar 2021 14:39:10
User entered 'No (N)'	System	18 Mar 2021 14:39:10

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-03-18T09:39:01-05:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '1c077a08-13e5-40ef-a32b-7945fae1d04c'	System	18 Mar 2021 14:39:10
User entered '18 Mar 2021 09:39:01'	System	18 Mar 2021 14:39:10

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-03-25T11:58:59-05:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b639bcd-f-0385-45c7-82cd-be04905170ce' User entered 'No (N)'	System	25 Mar 2021 16:59:13
	System	25 Mar 2021 16:59:13

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Have you been exposed to someone with 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-03-25T11:59:06-05:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b639bcd-f0385-45c7-82cd-be04905170ce'	System	25 Mar 2021 16:59:13
User entered 'No (N)'	System	25 Mar 2021 16:59:13

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-03-25T11:59:10-05:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'b639bcd-f0385-45c7-82cd-be04905170ce' User entered '25 Mar 2021 11:59:10'	System	25 Mar 2021 16:59:13
	System	25 Mar 2021 16:59:13

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-04-01T09:09:08-05:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'a65fa15c-244d-4e5b-a164-bf5f92b30790'	System	01 Apr 2021 14:09:22
User entered 'No (N)'	System	01 Apr 2021 14:09:22

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Have you been exposed to someone with 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-04-01T09:09:17-05:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'a65fa15c-244d-4e5b-a164-bf5f92b30790'	System	01 Apr 2021 14:09:22
User entered 'No (N)'	System	01 Apr 2021 14:09:22

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-04-01T09:09:20-05:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'a65fa15c-244d-4e5b-a164-bf5f92b30790'	System	01 Apr 2021 14:09:22
User entered '01 Apr 2021 09:09:20'	System	01 Apr 2021 14:09:22

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-04-12T11:59:51-05:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '0537d66c-2136-4852-a427-6605255070f6'	System	12 Apr 2021 17:00:21
User entered 'No (N)'	System	12 Apr 2021 17:00:21

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Have you been exposed to someone with 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-04-12T12:00:02-05:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '0537d66c-2136-4852-a427-6605255070f6'	System	12 Apr 2021 17:00:21
User entered 'No (N)'	System	12 Apr 2021 17:00:21

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-04-12T12:00:07-05:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '0537d66c-2136-4852-a427-6605255070f6'	System	12 Apr 2021 17:00:21
User entered '12 Apr 2021 12:00:07'	System	12 Apr 2021 17:00:21

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-04-18T20:13:05-05:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'fae63f9f-1fc2-4d2a-bcba-7accf1ba88fa' User entered 'No (N)'	System	19 Apr 2021 01:13:22

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Have you been exposed to someone with 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-04-18T20:13:10-05:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'fae63f9f-1fc2-4d2a-bcba-7accf1ba88fa' User entered 'No (N)'	System	19 Apr 2021 01:13:22

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-04-18T20:13:15-05:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: 'fae63f9f-1fc2-4d2a-bcba-7accf1ba88fa' User entered '18 Apr 2021 20:13:15'	System	19 Apr 2021 01:13:22
	System	19 Apr 2021 01:13:22

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-04-24T13:10:06-05:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '33845cc1-0a28-48f5-8392-c5c97af8d85c'	System	24 Apr 2021 18:10:16
User entered 'No (N)'	System	24 Apr 2021 18:10:16

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Have you been exposed to someone with 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-04-24T13:10:09-05:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '33845cc1-0a28-48f5-8392-c5c97af8d85c'	System	24 Apr 2021 18:10:16
User entered 'No (N)'	System	24 Apr 2021 18:10:16

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-04-24T13:10:12-05:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '33845cc1-0a28-48f5-8392-c5c97af8d85c'	System	24 Apr 2021 18:10:16
User entered '24 Apr 2021 13:10:12'	System	24 Apr 2021 18:10:16

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-04-29T18:26:32-05:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '5d136661-fc4f-4262-a140-c3ef335924e1' User entered 'No (N)'	System	29 Apr 2021 23:26:43
	System	29 Apr 2021 23:26:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

Have you been exposed to someone with 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 (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-04-29T18:26:35-05:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '5d136661-fc4f-4262-a140-c3ef335924e1' User entered 'No (N)'	System	29 Apr 2021 23:26:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-04-29T18:26:37-05:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '5d136661-fc4f-4262-a140-c3ef335924e1' User entered '29 Apr 2021 18:26:37'	System	29 Apr 2021 23:26:43
	System	29 Apr 2021 23:26:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 06:07:43

US3002259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:07:43
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 06:07:43

US3002259

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:51:34

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 09:27:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-03-05T18:27:35-06:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '41bd41ea-64a1-434c-a9da-cfe1d408e530'	System	06 Mar 2021 00:28:09
User entered 'No (N)'	System	06 Mar 2021 00:28:09

US3002259

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:51:34

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:27:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46BD0514-194C-4C19-9B56-6FFB56EBB357)', Time: '2021-03-05T18:27:41-06:00', User OID: 'PatientReportedOutcome (US3002259)', ODM File OID: '41bd41ea-64a1-434c-a9da-cfe1d408e530' User entered '05 Mar 2021 18:27:41'	System	06 Mar 2021 00:28:09
	System	06 Mar 2021 00:28:09

US3002259

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:59:42

US3002259

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '02 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:59:42

US3002259

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:59:42

US3002259

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:59:42

US3002259

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:59:46

US3002259

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 02:26:04
User entered 'I'	System	07 Dec 2020 20:59:46

US3002259

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) Kimberly Mueller (b) (4) (b) (4)	18 Jan 2021 04:38:42

US3002259

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '05 Jan 2021'	Kimberly Mueller (b) (4)	18 Jan 2021 04:38:42

US3002259

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Contact Made (CONTACT MADE)'	Kimberly Mueller (b) (4)	18 Jan 2021 04:38:42

US3002259

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) Kimberly Mueller (b) (4)	18 Jan 2021 04:38:42

US3002259

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) Kimberly Mueller (b) (4)	18 Jan 2021 04:38:50

US3002259

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User entered 'I'	System	18 Jan 2021 04:38:50

US3002259

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 22:19:24

US3002259

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 22:19:24

US3002259

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 22:19:24

US3002259

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 22:19:24

US3002259

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 22:19:26

US3002259

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User entered 'I'	System	03 Mar 2021 22:19:26

US3002259

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 13:12:09

US3002259

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:43:35
User entered '05 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 13:12:09

US3002259

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:43:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 13:12:09

US3002259

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:43:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 13:12:09

US3002259

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 13:12:12

US3002259

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User entered 'I'	System	23 Mar 2021 13:12:12

US3002259

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:20:11

US3002259

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:20:11

US3002259

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:20:11

US3002259

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User entered 'VISIT4'	System	26 Mar 2021 20:20:11

US3002259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:03:27
User closed query 'Per CDM, re-query: Thank you for your response, however, if a visit from Part A overlaps with a Visit from Part B and the visits occur on the same day, the data in assessments occurring in both visits must be identical. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	28 Apr 2021 09:17:55
User signature succeeded.	Brandon Essink (b) (4)	26 Apr 2021 15:01:21
Query 'Per CDM, re-query: Thank you for your response, however, if a visit from Part A overlaps with a Visit from Part B and the visits occur on the same day, the data in assessments occurring in both visits must be identical. Please reconcile. ' answered with 'UPDATED' (Site from DM).	Jessica Satorie (b) (4)	23 Apr 2021 20:24:24
Signature has been broken.	Jessica Satorie (b) (4)	23 Apr 2021 20:24:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessica Satorie (b) (4)	23 Apr 2021 20:24:05
User opened query 'Per CDM, re-query: Thank you for your response, however, if a visit from Part A overlaps with a Visit from Part B and the visits occur on the same day, the data in assessments occurring in both visits must be identical. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 08:51:29
User closed query 'Per Sponsor Review : Please note Visit 4 D209 and OL-D57 is done on the same date, Data should be same in Part A and Part B for Vital signs pages and all the respective pages to be completed, if done on the same day the data should be present in both the pages and should be same. Kindly reconcile and update appropriately. Thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 08:51:29

US3002259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

Were vital signs assessed?

Audit	User	Time (GMT)
Query 'Per Sponsor Review : Please note Visit 4 D209 and OL-D57 is done on the same date, Data should be same in Part A and Part B for Vital signs pages and all the respective pages to be completed, if done on the same day the data should be present in both the pages and should be same. Kindly reconcile and update appropriately. Thank you. ' answered with 'Vitals were not done at visit 4 per protocol and are not in source for visit 4. EDC must match source. ' (Site from DM).	Jessica Satorie (b) (4) (b) (4)	13 Apr 2021 15:04:28
User opened query 'Per Sponsor Review : Please note Visit 4 D209 and OL-D57 is done on the same date, Data should be same in Part A and Part B for Vital signs pages and all the respective pages to be completed, if done on the same day the data should be present in both the pages and should be same. Kindly reconcile and update appropriately. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	06 Apr 2021 12:38:20
User signature succeeded.	Brandon Essink (b) (4) (b) (4)	31 Mar 2021 20:36:05
User entered 'No (N)'	(b) (4), (b) (6) (b) (4)	31 Mar 2021 16:06:33

US3002259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:03:27
User signature succeeded.	Brandon Essink (b) (4)	26 Apr 2021 15:01:21
Signature has been broken.	Jessica Satorie (b) (4)	23 Apr 2021 20:24:05
User entered '26 Mar 2021' reason for change: Data Entry Error	Jessica Satorie (b) (4)	23 Apr 2021 20:24:05
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 16:06:33

US3002259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:03:27
User signature succeeded.	Brandon Essink (b) (4)	26 Apr 2021 15:01:21
Signature has been broken.	Jessica Satorie (b) (4)	23 Apr 2021 20:24:05
User entered '14:14' reason for change: Data Entry Error	Jessica Satorie (b) (4)	23 Apr 2021 20:24:05
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 16:06:33

US3002259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:03:27
User entered '26 Mar 2021 14:14'	System	23 Apr 2021 20:24:05
User entered empty.	System	31 Mar 2021 16:06:33

US3002259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:03:27
User signature succeeded.	Brandon Essink (b) (4)	26 Apr 2021 15:01:21
Signature has been broken.	Jessica Satorie (b) (4)	23 Apr 2021 20:24:05
User entered '37.2' C reason for change: Data Entry Error	Jessica Satorie (b) (4)	23 Apr 2021 20:24:05
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 16:06:33

US3002259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:03:27
User signature succeeded.	Brandon Essink (b) (4)	26 Apr 2021 15:01:21
Signature has been broken.	Jessica Satorie (b) (4)	23 Apr 2021 20:24:05
User entered 'Oral (Oral)' reason for change: Data Entry Error	Jessica Satorie (b) (4)	23 Apr 2021 20:24:05
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 16:06:33

US3002259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:03:27
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:06:33

US3002259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:03:27
User signature succeeded.	Brandon Essink (b) (4)	26 Apr 2021 15:01:21
Signature has been broken.	Jessica Satorie (b) (4)	23 Apr 2021 20:24:05
User entered '81' reason for change: Data Entry Error	Jessica Satorie (b) (4)	23 Apr 2021 20:24:05
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 16:06:33

US3002259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:03:27
User entered 'bpm'	System	23 Apr 2021 20:24:05
User entered empty.	System	31 Mar 2021 16:06:33

US3002259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:03:27
User signature succeeded.	Brandon Essink (b) (4)	26 Apr 2021 15:01:21
Signature has been broken.	Jessica Satorie (b) (4)	23 Apr 2021 20:24:05
User entered '16' reason for change: Data Entry Error	Jessica Satorie (b) (4)	23 Apr 2021 20:24:05
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 16:06:33

US3002259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:03:27
User entered 'breaths/min'	System	23 Apr 2021 20:24:05
User entered empty.	System	31 Mar 2021 16:06:33

US3002259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:03:27
User signature succeeded.	Brandon Essink (b) (4)	26 Apr 2021 15:01:21
Signature has been broken.	Jessica Satorie (b) (4)	23 Apr 2021 20:24:05
User entered '132' reason for change: Data Entry Error	Jessica Satorie (b) (4)	23 Apr 2021 20:24:05
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 16:06:33

US3002259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:03:27
User entered 'mmHg'	System	23 Apr 2021 20:24:05
User entered empty.	System	31 Mar 2021 16:06:33

US3002259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:03:27
User signature succeeded.	Brandon Essink (b) (4)	26 Apr 2021 15:01:21
Signature has been broken.	Jessica Satorie (b) (4)	23 Apr 2021 20:24:05
User entered '74' reason for change: Data Entry Error	Jessica Satorie (b) (4)	23 Apr 2021 20:24:05
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 16:06:33

US3002259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:03:27
User entered 'mmHg'	System	23 Apr 2021 20:24:05
User entered empty.	System	31 Mar 2021 16:06:33

US3002259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:03:27

US3002259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:03:27

US3002259

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:20:19

US3002259

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:20:19

US3002259

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:20:39

US3002259

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:20:39

US3002259

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:34

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered '14:16'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:20:39

US3002259

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User entered '26 Mar 2021 14:16'	System	26 Mar 2021 20:20:39

US3002259

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:20:42

US3002259

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:47:14
User entered 'I'	System	26 Mar 2021 20:20:42

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 18:35:58

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:13
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 18:35:58

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
DataPoint Verified.	(b) (4)	02 Feb 2021 17:12:13
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Jan 2021 18:35:58

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 18:35:58

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:34

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
DataPoint Verified.	(b) (4)	02 Feb 2021 17:12:21
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 18:36:10

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:34

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:51:00
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:48:34

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:34

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 18:36:10

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:34

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:51:00
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:48:34

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:34

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:21
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 18:36:10

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:34

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:21
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	19 Jan 2021 18:36:10

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:34

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
DataPoint Verified.	(b) (4)	02 Feb 2021 17:12:21
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 09:10:23
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	19 Jan 2021 18:36:10

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:34

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
DataPoint Verified.	(b) (4)	02 Feb 2021 17:12:21
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	20 Jan 2021 09:10:23
User entered 'Placebo (Placebo)'	System	19 Jan 2021 18:36:10
	(b) (4), (b) (6)	

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:34

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 18:36:10

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:34

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered '1'	System	19 Jan 2021 18:36:10

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:34

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'I'	System	19 Jan 2021 18:36:10

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:34

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:30
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:30
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:34

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered empty.	System	20 Jan 2021 18:22:53
DataPoint set to visible.	System	19 Jan 2021 18:36:10

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:34

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:30
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:30
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:34

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered empty.	System	20 Jan 2021 18:22:53
DataPoint set to visible.	System	19 Jan 2021 18:36:10

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
DataPoint Verified.	(b) (4)	02 Feb 2021 17:12:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:51:07
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:30
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	20 Jan 2021 18:22:53
User entered '20 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:30
User entered '10:55'	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered '20 Jan 2021 10:55'	System	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:30
User entered '36.8' C	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
DataPoint Verified.	(b) (4)	02 Feb 2021 17:12:30
User entered 'Oral (Oral)'	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:30
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:30
User entered '60'	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'bpm'	System	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:30
User entered '15'	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'breaths/min'	System	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:30
User entered '140'	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'mmHg'	System	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:30
User entered '82'	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'mmHg'	System	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:34

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:30
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:30
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:34

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered empty.	System	20 Jan 2021 18:22:53
DataPoint set to visible.	System	19 Jan 2021 18:36:10

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:51:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:30
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	20 Jan 2021 18:22:53
User entered '20 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:30
User entered '11:49'	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered '20 Jan 2021 11:49'	System	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:30
User entered '36.8' C	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:12:30
User entered 'Oral (Oral)'	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:30
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:30
User entered '63'	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'bpm'	System	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:30
User entered '15'	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'breaths/min'	System	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:30
User entered '158'	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'mmHg'	System	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:30
User entered '88'	(b) (4), (b) (6)	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'mmHg'	System	20 Jan 2021 18:22:53

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:23:03

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
Query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 15:42:06
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	20 Jan 2021 18:23:03
User entered '20 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 18:23:03

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 18:23:31

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:50
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 18:23:31

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

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)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:50
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 18:23:31

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'mRNA-1273'	System	20 Jan 2021 18:23:31
DataPoint set to visible.	System	19 Jan 2021 18:36:10

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:12:50
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	25 Jan 2021 09:59:08
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered with 'data correct' (Site from System).	(b) (4), (b) (6)	20 Jan 2021 18:23:37
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	20 Jan 2021 18:23:31
User entered '20 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 18:23:31

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:50
User entered '11:13'	(b) (4), (b) (6)	20 Jan 2021 18:23:31

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered '20 Jan 2021 11:13'	System	20 Jan 2021 18:23:31

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:12:50
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	20 Jan 2021 18:23:31

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:12:50
User entered 'ONCE'	System	20 Jan 2021 18:23:31

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'INTRAMUSCULAR'	System	20 Jan 2021 18:23:31

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:13:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 18:36:17

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:34

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:13:12
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 18:36:17

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:34

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:13:12
User entered '12:02'	(b) (4), (b) (6)	19 Jan 2021 18:36:17

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered '19 Jan 2021 12:02'	System	19 Jan 2021 18:36:17

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:51:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:13:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 18:36:25

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:51:34

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:13:17
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 18:36:25

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:51:34

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:13:17
User entered '12:04'	(b) (4), (b) (6)	19 Jan 2021 18:36:25

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:51:34

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered '19 Jan 2021 12:04'	System	19 Jan 2021 18:36:25

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:13:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 18:36:29

US3002259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'I'	System	19 Jan 2021 18:36:29

US3002259

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:47:29

US3002259

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:47:29

US3002259

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:47:29

US3002259

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 13:47:29

US3002259

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:14:11

US3002259

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'I'	System	18 Feb 2021 14:14:11

US3002259

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered '1'	System	18 Feb 2021 14:14:11
DataPoint set to visible.	System	18 Feb 2021 14:14:11

US3002259

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:14:20

US3002259

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:14:20

US3002259

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:14:20

US3002259

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'OLD29'	System	18 Feb 2021 14:14:20

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered '13:02'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered '17 Feb 2021 13:02'	System	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered '36.8' C	(b) (4), (b) (6)	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered '60'	(b) (4), (b) (6)	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'bpm'	System	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered '16'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'breaths/min'	System	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered '130'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'mmHg'	System	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered '70'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'mmHg'	System	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered '14:13'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered '17 Feb 2021 14:13'	System	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered '36.8' C	(b) (4), (b) (6)	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered '60'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'bpm'	System	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered '14'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'breaths/min'	System	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered '126'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'mmHg'	System	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered '72'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'mmHg'	System	18 Feb 2021 14:15:27

US3002259

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:15:37

US3002259

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:15:37

US3002259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:15:49

US3002259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered empty.	(b) (4)	18 Feb 2021 14:15:49
	(b) (4), (b) (6)	

US3002259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

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)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 14:15:49

US3002259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'mRNA-1273'	System	18 Feb 2021 14:15:49
DataPoint set to visible.	System	18 Feb 2021 14:14:11

US3002259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:15:49

US3002259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered '13:43'	(b) (4), (b) (6)	18 Feb 2021 14:15:49

US3002259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered '17 Feb 2021 13:43'	System	18 Feb 2021 14:15:49

US3002259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:15:49

US3002259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'ONCE'	System	18 Feb 2021 14:15:49

US3002259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:34

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'INTRAMUSCULAR'	System	18 Feb 2021 14:15:49

US3002259

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	19 Feb 2021 15:29:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:15:51

US3002259

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'I'	System	18 Feb 2021 14:15:51

US3002259

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	01 Apr 2021 19:08:04
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	31 Mar 2021 23:39:40

US3002259

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	01 Apr 2021 19:08:04
User entered '24 Feb 2021'	Jessica Satorie (b) (4)	31 Mar 2021 23:39:40

US3002259

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	01 Apr 2021 19:08:04
User entered 'Contact Made (CONTACT MADE)'	Jessica Satorie (b) (4)	31 Mar 2021 23:39:40

US3002259

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	01 Apr 2021 19:08:04
User entered empty.	Jessica Satorie (b) (4)	31 Mar 2021 23:39:40

US3002259

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:19:11

US3002259

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'I'	System	26 Mar 2021 20:19:11

US3002259

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:19:23

US3002259

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:19:23

US3002259

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:19:23

US3002259

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'OLD57'	System	26 Mar 2021 20:19:23

US3002259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:19:42

US3002259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:19:42

US3002259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered '14:14'	(b) (4), (b) (6)	26 Mar 2021 20:19:42

US3002259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered '26 Mar 2021 14:14'	System	26 Mar 2021 20:19:42

US3002259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered '37.2' C	(b) (4), (b) (6)	26 Mar 2021 20:19:42

US3002259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:19:42

US3002259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:19:42

US3002259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered '81'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:19:42

US3002259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'bpm'	System	26 Mar 2021 20:19:42

US3002259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered '16'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:19:42

US3002259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'breaths/min'	System	26 Mar 2021 20:19:42

US3002259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered '132'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:19:42

US3002259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'mmHg'	System	26 Mar 2021 20:19:42

US3002259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered '74'	(b) (4), (b) (6)	26 Mar 2021 20:19:42

US3002259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered 'mmHg'	System	26 Mar 2021 20:19:42

US3002259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58

US3002259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:34

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58

US3002259

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:19:48

US3002259

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 20:19:48

US3002259

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:19:56

US3002259

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:19:56

US3002259

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:34

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:45:51
User entered '14:16'	(b) (4), (b) (6)	26 Mar 2021 20:19:56

US3002259

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:56:58
User entered '26 Mar 2021 14:16'	System	26 Mar 2021 20:19:56

US3002259

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:51:34

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:58:25
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	04 Dec 2020 15:57:39
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 17:58:50

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle weakness conditions, PT: Muscular weakness, LLT: Lower extremities weakness of - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 14:29:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 14:29:54
Data point term sent to Coder	System	04 Dec 2020 15:59:32
User entered 'Worsening bilateral leg weakness'	(b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '19 Nov 2020'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[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 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Dec 2020 15:58:33

US3002259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:27
User entered 'USA-US005-2020-mRNA-1273-P301000011'	System	09 Dec 2020 18:26:21
User entered 'New'	(b) (4), (b) (6)	09 Dec 2020 18:26:21

US3002259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User coded data point as SOC: Nervous system disorders, HLGT: Increased intracranial pressure and hydrocephalus, HLT: Hydrocephalic conditions, PT: Hydrocephalus, LLT: Hydrocephalus - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	08 Dec 2020 21:21:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Dec 2020 21:21:53
Data point term sent to Coder	System	08 Dec 2020 21:21:07
User entered 'hydrocephalus'	Tiffany Nemecek (b) (4) (b) (4)	08 Dec 2020 21:20:34

US3002259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4)	08 Dec 2020 21:20:34
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'No (N)'	Tiffany Nemecek (b) (4)	08 Dec 2020 21:20:34
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'No (N)'	Tiffany Nemecek (b) (4)	08 Dec 2020 21:20:34
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '06 Dec 2020' reason for change: Data Entry Error	Tiffany Nemecek (b) (4)	08 Dec 2020 21:26:02
	(b) (4)	
User entered '07 Dec 2020'	Tiffany Nemecek (b) (4)	08 Dec 2020 21:20:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Tiffany Nemecek (b) (4)	08 Dec 2020 21:20:34
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Dec 2020 21:20:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Kimberly Mueller (b) (4)	06 Jan 2021 19:54:24
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4)	08 Dec 2020 21:20:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '15 Dec 2020' reason for change: Data Entry Error	Kimberly Mueller (b) (4)	06 Jan 2021 19:54:24
	(b) (4)	
User entered empty.	Tiffany Nemecek (b) (4)	08 Dec 2020 21:20:34
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Tiffany Nemecek (b) (4)	08 Dec 2020 21:20:34
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 22:25:58
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 16:04:55
User entered empty.	System	08 Dec 2020 21:20:34

US3002259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 20:32:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 20:32:20
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Jessica Satorie (b) (4)	09 Dec 2020 20:32:20
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 21:20:34
User entered empty.	Tiffany Nemecek (b) (4)	08 Dec 2020 21:20:34
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4)	08 Dec 2020 21:20:34
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Tiffany Nemecek (b) (4)	08 Dec 2020 21:20:34
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Tiffany Nemecek (b) (4)	08 Dec 2020 21:20:34
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	08 Jan 2021 14:44:14
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Med records sent to Safety_Moderna@iqvia.com on 07Jan2021.' (Site from Safety).	Kimberly Mueller (b) (4) (b) (4)	07 Jan 2021 22:50:38
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 16:08:05
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	10 Dec 2020 06:08:09
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'admission date is entered' (Site from System).	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 20:32:47
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	08 Dec 2020 21:20:34
User entered '1'	Tiffany Nemecek (b) (4) (b) (4)	08 Dec 2020 21:20:34

US3002259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '07 Dec 2020'	Tiffany Nemecek (b) (4)	08 Dec 2020 21:20:34
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '22 Dec 2020' reason for change: Data Entry Error	Kimberly Mueller (b) (4)	07 Jan 2021 22:16:36
	(b) (4)	
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 15:37:26
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'done' (Site from Safety).	Kimberly Mueller (b) (4)	06 Jan 2021 19:54:31
	(b) (4)	
User entered '16 Dec 2020' reason for change: Data Entry Error	Kimberly Mueller (b) (4)	06 Jan 2021 19:54:24
	(b) (4)	
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 16:07:19
User entered empty.	Tiffany Nemecek (b) (4)	08 Dec 2020 21:20:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'No (N)'	Tiffany Nemecek (b) (4)	08 Dec 2020 21:20:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Tiffany Nemecek (b) (4)	08 Dec 2020 21:20:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Tiffany Nemecek (b) (4)	08 Dec 2020 21:20:34
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Tiffany Nemecek (b) (4)	08 Dec 2020 21:20:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Tiffany Nemecek (b) (4)	08 Dec 2020 21:20:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:37:29
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' answered with 'done' (Site from Safety).	Kimberly Mueller (b) (4) (b) (4)	06 Jan 2021 19:54:41
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 16:06:18
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' canceled (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 21:09:53
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 20:32:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 20:32:20
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 20:32:20
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 20:17:32
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 21:20:34
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	08 Dec 2020 21:20:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:09:56
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 20:32:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 20:32:20
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 20:32:20
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 20:17:45
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 21:20:34
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	08 Dec 2020 21:20:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Tiffany Nemecek (b) (4)	08 Dec 2020 21:20:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Tiffany Nemecek (b) (4)	08 Dec 2020 21:20:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '1'	Tiffany Nemecek (b) (4)	08 Dec 2020 21:20:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Kimberly Mueller (b) (4)	06 Jan 2021 19:54:24
	(b) (4)	
User entered '0'	Tiffany Nemecek (b) (4)	08 Dec 2020 21:20:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:37:33
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'done' (Site from Safety).	Kimberly Mueller (b) (4) (b) (4)	06 Jan 2021 19:54:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Kimberly Mueller (b) (4) (b) (4)	06 Jan 2021 19:54:24
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 16:05:16
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Tiffany Nemecek (b) (4) (b) (4)	08 Dec 2020 21:20:34

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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 12:36:34
	(b) (4)	
User entered empty.	Tiffany Nemecek (b) (4)	08 Dec 2020 21:20:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User closed query 'PV Query: It was reported the subject tested positive for COVID-19, if this was a confirmed Symptomatic case of COVID-19 please consider adding COVID-19 as a separate event, else clarify.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	08 Jan 2021 14:44:45
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 14:44:37
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)	08 Jan 2021 14:44:25
User closed query 'PV Query: Please provide details of the COVID-19 testing performed during hospital admission, including date of collection and type of testing.' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 14:44:21
Query 'PV Query: It was reported the subject tested positive for COVID-19, if this was a confirmed Symptomatic case of COVID-19 please consider adding COVID-19 as a separate event, else clarify.' answered with 'done' (Site from Safety).	Kimberly Mueller (b) (4) (b) (4)	07 Jan 2021 22:57:07
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'Covid-19' (Site from Safety).	Kimberly Mueller (b) (4) (b) (4)	07 Jan 2021 22:49:52
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 'Ventriculoperitoneal shunt placed 15Dec2020. Solumedrol 500 mg IV daily 14Dec2020 to 18Dec2020. Eliquis 5 mg PO BID started 25Dec2020.' (Site from Safety).	Kimberly Mueller (b) (4) (b) (4)	07 Jan 2021 22:21:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide details of the COVID-19 testing performed during hospital admission, including date of collection and type of testing.' answered with 'Nasopharyngeal swab done 16Dec2020 during hospitalization. Records requested from separate hospital ED visits at different facility on Dec 4 and 6, 2020.' (Site from Safety).	Kimberly Mueller (b) (4)	07 Jan 2021 22:16:43
User entered 'Pt was admitted to hospital for hydrocephalus on 07Dec2020 thought to be related to encephalopathy brought on by Covid-19. Subject tested positive for Covid-19 on December 4, 6, and 16. He had VP shunt placed Dec 15 with some improvement of weakness and gait. He was admitted to Rehab Facility on Dec 22 for PT/OT and was discharged on Dec 28. Via phone pt. states weakness had totally resolved on Jan 02, 2020.' reason for change: Data Entry Error	Kimberly Mueller (b) (4)	07 Jan 2021 22:16:36
User opened query 'PV Query: It was reported the subject tested positive for COVID-19, if this was a confirmed Symptomatic case of COVID-19 please consider adding COVID-19 as a separate event, else clarify.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 16:09:01
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 16:07:01
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)	15 Dec 2020 16:05:43
User opened query 'PV Query: Please provide details of the COVID-19 testing performed during hospital admission, including date of collection and type of testing.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 16:04:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT. WENT INTO THE ER ON 06DEC2020 FOR BILATERAL LEG WEAKNESS. PT. WAS DIAGNOSED WITH HYDROCEPHALUS. MEDICAL RECORDS PENDING AS PT. IS STILL IN THE HOSPITAL. PT. IS COVID POSITIVE ALSO, BUT UNABLE TO COME IN FOR AN ILLNESS VISIT BECAUSE THEY ARE HOSPITALIZED.' reason for change: Data Entry Error	Tiffany Nemecek (b) (4)	08 Dec 2020 21:37:32
User entered 'PT. WENT INTO THE ER ON 07DEC2020 for bilateral LEG WEAKNESS. PT. WAS DIAGNOSED WITH HYDROCEPHALUS. MEDICAL RECORDS PENDING AS PT. IS STILL IN THE HOSPITAL. PT. IS COVID POSITIVE ALSO, but unable to come in for an illness visit because they are hospitalized.' reason for change: Data Entry Error	Tiffany Nemecek (b) (4)	08 Dec 2020 21:21:50
User entered 'Pt. went into the ER on 07DEC2020 leg weakness. Pt. was diagnosed with hydrocephalus. Medical Records pending as pt. is still in the hospital. Pt. is COVID positive also.'	Tiffany Nemecek (b) (4)	08 Dec 2020 21:20:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 21:20:34

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Folder: Adverse Events

Form: Adverse Events (2)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 21:20:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:34

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Dec 2020 21:20:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 15:05:56
User entered	(b) (4), (b) (6)	08 Jan 2021 15:05:50
'USA-US005-2020-mRNA-1273-P301000011'		

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
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.	(b) (4) Coder Import (b) (4)	07 Jan 2021 22:53:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Jan 2021 22:53:45
Data point term sent to Coder	System	07 Jan 2021 22:53:21
User entered 'covid-19'	Kimberly Mueller (b) (4) (b) (4)	07 Jan 2021 22:52:53

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Yes (Y)'	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'No (N)'	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Yes (Y)'	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '04 Dec 2020'	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Jan 2021 22:52:53

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'No (N)'	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '19 Dec 2020'	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Jan 2021 22:52:53

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:23:52
reason for change: Data Entry Error	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'No (N)'	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '1'	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:23:52
reason for change: Data Entry Error	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[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 12:36:34
	(b) (4)	
User entered 'atrial fibrillation' reason for change:	Kimberly Mueller (b) (4)	08 Jan 2021 14:23:52
Data Entry Error	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	07 Jan 2021 22:52:53
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Jan 2021 22:52:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:51:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Jan 2021 22:52:53

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	08 Jan 2021 14:23:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Jan 2021 14:23:40
Data point term sent to Coder	System	08 Jan 2021 14:22:55
User entered 'atrial fibrillation'	Kimberly Mueller (b) (4) (b) (4)	08 Jan 2021 14:22:54

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Yes (Y)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'No (N)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'No (N)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '06 Dec 2020'	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 14:22:54

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Yes (Y)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 14:22:54

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'No (N)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Brandon Essink (b) (4)	11 Jan 2021 15:40:31
reason for change: Data Entry Error	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '1'	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[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 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Potentially triggered by covid 19 infection per treating physician' reason for change:	(b) (4)	
Data Entry Error	Brandon Essink (b) (4)	11 Jan 2021 15:40:55
User entered 'caused by Covid-19'	(b) (4)	
	Kimberly Mueller (b) (4)	08 Jan 2021 14:22:54
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Jan 2021 14:22:54

US3002259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:51:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Jan 2021 14:22:54

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary retention, LLT: Urinary retention - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	04 Feb 2021 14:21:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 14:21:46
Data point term sent to Coder	System	04 Feb 2021 14:20:48
User entered 'URINARY RETENTION'	Kimberly Mueller (b) (4) (b) (4)	04 Feb 2021 14:20:08

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Yes (Y)'	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'No (N)'	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'No (N)'	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '16 Dec 2020'	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 14:20:08

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 06:24:28
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' answered with 'ongoing because subject still takes Flomax for this indication' (Site from DM).	Kimberly Mueller (b) (4)	16 Mar 2021 23:31:11
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	20 Feb 2021 03:30:56
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 14:20:08

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'No (N)'	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '1'	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Kimberly Mueller (b) (4) (b) (4)	04 Feb 2021 14:20:08

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[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 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = SUBJECT HAD FOLEY CATHETER. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 20:03:18
Query 'Per DM CLR: Narrative = SUBJECT HAD FOLEY CATHETER. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'added' (Site from DM).	Kimberly Mueller (b) (4)	16 Mar 2021 23:31:16
User opened query 'Per DM CLR: Narrative = SUBJECT HAD FOLEY CATHETER. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	20 Feb 2021 03:30:47
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Subject had foley catheter during hospitalization for covid-19/hydrocephalus due to urinary retention, then successful voiding trial outpatient. He continues on Flomax.'	Kimberly Mueller (b) (4)	04 Feb 2021 14:20:08

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Feb 2021 14:20:08

US3002259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:51:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Feb 2021 14:20:08

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Water soluble vitamin deficiencies, PT: Vitamin B12 deficiency, LLT: Vitamin B12 deficiency - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	04 Feb 2021 14:22:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 14:22:49
Data point term sent to Coder	System	04 Feb 2021 14:21:49
User entered 'Vitamin B-12 deficiency'	Kimberly Mueller (b) (4) (b) (4)	04 Feb 2021 14:21:08

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Yes (Y)'	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'No (N)'	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'No (N)'	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '16 Dec 2020'	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 14:21:08

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Yes (Y)'	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 14:21:08

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'No (N)'	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '1'	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '0'	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[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 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	04 Feb 2021 14:21:08
	(b) (4)	

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Feb 2021 14:21:08

US3002259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:51:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Feb 2021 14:21:08

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 21:20:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 21:20:08
Data point term sent to Coder	System	30 Mar 2021 21:19:18
User entered 'Worsening hypertension'	(b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User entered empty.	System	30 Mar 2021 21:18:53

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:18:53

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User entered empty.	System	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User closed query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade 1. Please confirm/update the severity. Else, clarify. '(Site from DM).	(b) (4), (b) (6)	27 Apr 2021 17:27:29
Query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade 1. Please confirm/update the severity. Else, clarify. ' answered with 'correct as entered '(Site from DM).	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 13:53:05
User opened query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade 1. Please confirm/update the severity. Else, clarify. '(Site from DM).	(b) (4), (b) (6)	04 Apr 2021 10:49:01
User signature succeeded.	Brandon Essink (b) (4) (b) (4)	31 Mar 2021 20:36:05
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered 'I'	(b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User entered '0'	System	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40
User entered '0'	System	30 Mar 2021 21:18:53

US3002259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:51:34

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:58:40

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:51:34

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:58:25
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:25:54
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:59:07

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:34

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 18:01:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 18:01:46
Data point term sent to Coder	System	08 Sep 2020 18:00:44
User entered 'Metoprolol'	(b) (4), (b) (6)	08 Sep 2020 17:59:50

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 17:59:50

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Hypertension'	(b) (4), (b) (6)	08 Sep 2020 17:59:50

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '25'	(b) (4), (b) (6)	08 Sep 2020 17:59:50

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Sep 2020 17:59:50

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 17:59:50

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Sep 2020 17:59:50

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 17:59:50

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 17:59:50

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 17:59:50

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:59:50

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 17:59:50

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 17:59:50

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 17:59:50

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:59:50

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 17:59:50

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 17:59:50

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 17:59:50

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Sep 2020 18:01:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 18:01:45
Data point term sent to Coder	System	08 Sep 2020 18:00:44
User entered 'Hydrochlorothiazide'	(b) (4), (b) (6)	08 Sep 2020 18:00:32

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 18:00:32

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Hypertension'	(b) (4), (b) (6)	08 Sep 2020 18:00:32

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '25'	(b) (4), (b) (6)	08 Sep 2020 18:00:32

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Sep 2020 18:00:32

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:00:32

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Sep 2020 18:00:32

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:00:32

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 18:00:32

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:00:32

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'un UNK 2008'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:00:32

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 18:00:32

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:00:32

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:00:32

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:00:32

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:00:32

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:00:32

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 18:00:32

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:34

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 20:38:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 20:38:48
Data point term sent to Coder Coding entries removed.	System Kimberly Mueller (b) (4)	18 Nov 2020 20:37:58 18 Nov 2020 20:37:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 18:02:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 18:02:51
Data point term sent to Coder User entered 'Lisinopril'	System (b) (4), (b) (6)	08 Sep 2020 18:01:47 08 Sep 2020 18:00:58

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 18:00:58

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User closed query 'Per DM CLR: Please review Indication and please note, this medication is not typically used as treatment for Hyperlipidemia. Please review and update indication as appropriate or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:41:39
Query 'Per DM CLR: Please review Indication and please note, this medication is not typically used as treatment for Hyperlipidemia. Please review and update indication as appropriate or provide clarification. ' answered with 'corrected' (Site from DM).	Kimberly Mueller (b) (4) (b) (4)	18 Nov 2020 20:39:07
User entered 'hypertension' reason for change: Data Entry Error	Kimberly Mueller (b) (4) (b) (4)	18 Nov 2020 20:37:21
User opened query 'Per DM CLR: Please review Indication and please note, this medication is not typically used as treatment for Hyperlipidemia. Please review and update indication as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 22:05:23
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	08 Sep 2020 18:00:58

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '20'	(b) (4), (b) (6)	08 Sep 2020 18:00:58

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Sep 2020 18:00:58

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:00:58

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Sep 2020 18:00:58

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:00:58

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 18:00:58

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:00:58

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:00:58

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 18:00:58

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:00:58

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:00:58

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:00:58

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:00:58

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:00:58

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 18:00:58

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Sep 2020 18:02:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 18:02:51
Data point term sent to Coder	System	08 Sep 2020 18:01:47
User entered 'Escitalopram'	(b) (4), (b) (6)	08 Sep 2020 18:01:21

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 18:01:21

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Anxiety'	(b) (4), (b) (6)	08 Sep 2020 18:01:21

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '20'	(b) (4), (b) (6)	08 Sep 2020 18:01:21

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Sep 2020 18:01:21

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:01:21

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Sep 2020 18:01:21

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:01:21

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 18:01:21

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:01:21

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User closed query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH record. Please reconcile and update applicable details as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 06:05:32
Query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH record. Please reconcile and update applicable details as appropriate. Otherwise, clarify. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 13:28:07
User entered 'UN Jun 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 13:28:01
User opened query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH record. Please reconcile and update applicable details as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 22:04:58
User entered 'un Jan 2020'	(b) (4), (b) (6)	08 Sep 2020 18:01:21

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 18:01:21

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:01:21

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:01:21

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:01:21

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:01:21

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:01:21

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 18:01:21

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 18:20:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 18:20:40
Data point term sent to Coder	System	11 Sep 2020 18:19:38
User entered 'acetaminophen'	Brandon Essink (b) (4)	11 Sep 2020 18:19:24

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	Brandon Essink (b) (4)	11 Sep 2020 18:19:24

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'chronic back pain'	Brandon Essink (b) (4)	11 Sep 2020 18:19:24

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '1000'	Brandon Essink (b) (4)	11 Sep 2020 18:19:24

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'mg (mg)'	Brandon Essink (b) (4)	11 Sep 2020 18:19:24

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:34

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Brandon Essink (b) (4)	11 Sep 2020 18:19:24

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'as needed (PRN)'	Brandon Essink (b) (4)	11 Sep 2020 18:19:24

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:34

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Brandon Essink (b) (4)	11 Sep 2020 18:19:24

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Sep 2020 18:19:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 18:19:32
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Brandon Essink (b) (4)	11 Sep 2020 18:19:32
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Sep 2020 18:19:24
User entered empty.	System	11 Sep 2020 18:19:24
	Brandon Essink (b) (4)	11 Sep 2020 18:19:24
	(b) (4)	

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Brandon Essink (b) (4)	11 Sep 2020 18:19:24

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'un UNK 2015'	Brandon Essink (b) (4)	11 Sep 2020 18:19:24

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	Brandon Essink (b) (4)	11 Sep 2020 18:19:24

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	Brandon Essink (b) (4)	11 Sep 2020 18:19:24

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Brandon Essink (b) (4)	11 Sep 2020 18:19:24

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	Brandon Essink (b) (4)	11 Sep 2020 18:19:24

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 18:19:24

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 18:19:24

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 18:19:24

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:12
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 18:52:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 18:52:10
Data point term sent to Coder	System	02 Nov 2020 22:46:29
User entered 'Influenza vaccine'	(b) (4), (b) (6)	02 Nov 2020 22:45:34

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:12
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:45:34

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:12
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Influenza prevention'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:45:34

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:12
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0.5'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:45:34

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:12
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:45:34

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:12
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:45:34

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:12
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:45:34

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:12
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:45:34

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:12
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	02 Nov 2020 22:45:34

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:12
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:45:34

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:12
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:45:34

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:12
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:45:34

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:12
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:45:34

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:12
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:45:34

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:12
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:45:34

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:12
User entered empty.	System	02 Nov 2020 22:45:34

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:12
User entered empty.	System	02 Nov 2020 22:45:34

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:12
User entered empty.	System	02 Nov 2020 22:45:34

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12, ATC: VITAMIN B1, PLAIN, PRODUCT: THIAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 16:17:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 16:17:41
Data point term sent to Coder	System	08 Jan 2021 14:38:59
User entered 'THIAMINE'	Kimberly Mueller (b) (4)	08 Jan 2021 14:38:15

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:38:15

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 07:13:17
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'AE added' (Site from DM).	Kimberly Mueller (b) (4) (b) (4)	04 Feb 2021 14:21:26
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 08:06:33
User entered 'vitamin b-12 deficiency'	Kimberly Mueller (b) (4) (b) (4)	08 Jan 2021 14:38:15

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '100'	Kimberly Mueller (b) (4)	08 Jan 2021 14:38:15

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'mg (mg)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:38:15

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Kimberly Mueller (b) (4)	08 Jan 2021 14:38:15

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'once daily (QD)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:38:15

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Kimberly Mueller (b) (4)	08 Jan 2021 14:38:15

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Oral (ORAL)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:38:15

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Kimberly Mueller (b) (4)	08 Jan 2021 14:38:15

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '22 Dec 2020'	Kimberly Mueller (b) (4)	08 Jan 2021 14:38:15

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	Kimberly Mueller (b) (4)	08 Jan 2021 14:38:15

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:38:15

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Kimberly Mueller (b) (4)	08 Jan 2021 14:38:15

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:38:15

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 14:38:15

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 14:38:15

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Jan 2021 14:38:15

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:34

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 14:40:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	08 Jan 2021 14:40:41
Data point term sent to Coder	System	08 Jan 2021 14:39:59
User entered 'flomax'	Kimberly Mueller (b) (4)	08 Jan 2021 14:39:02
	(b) (4)	

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:39:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 07:14:25
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'AE added' (Site from DM).	Kimberly Mueller (b) (4) (b) (4)	04 Feb 2021 14:21:36
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 08:06:48
User entered 'urinary retention'	Kimberly Mueller (b) (4) (b) (4)	08 Jan 2021 14:39:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0.4'	Kimberly Mueller (b) (4)	08 Jan 2021 14:39:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'mg (mg)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:39:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Kimberly Mueller (b) (4)	08 Jan 2021 14:39:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'once daily (QD)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:39:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Kimberly Mueller (b) (4)	08 Jan 2021 14:39:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Oral (ORAL)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:39:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Kimberly Mueller (b) (4)	08 Jan 2021 14:39:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '22 Dec 2020'	Kimberly Mueller (b) (4)	08 Jan 2021 14:39:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	Kimberly Mueller (b) (4)	08 Jan 2021 14:39:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:39:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Kimberly Mueller (b) (4)	08 Jan 2021 14:39:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:39:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 14:39:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 14:39:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Jan 2021 14:39:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 14:42:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 14:42:40
Data point term sent to Coder	System	08 Jan 2021 14:42:00
User entered 'eliquis'	Kimberly Mueller (b) (4)	08 Jan 2021 14:41:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:41:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'atrial fibrillation'	Kimberly Mueller (b) (4)	08 Jan 2021 14:41:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '5'	Kimberly Mueller (b) (4)	08 Jan 2021 14:41:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'mg (mg)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:41:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:34

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Kimberly Mueller (b) (4)	08 Jan 2021 14:41:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'once daily (QD)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:41:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Kimberly Mueller (b) (4)	08 Jan 2021 14:41:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Oral (ORAL)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:41:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Kimberly Mueller (b) (4)	08 Jan 2021 14:41:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '25 Dec 2020'	Kimberly Mueller (b) (4)	08 Jan 2021 14:41:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	Kimberly Mueller (b) (4)	08 Jan 2021 14:41:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Yes (Y)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:41:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Kimberly Mueller (b) (4)	08 Jan 2021 14:41:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:41:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 14:41:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 14:41:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Jan 2021 14:41:02

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:16
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE SODIUM SUCCINATE, PRODUCTSYNONYM: SOLUMEDROL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Jan 2021 16:09:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Jan 2021 16:09:40
Data point term sent to Coder	System	08 Jan 2021 14:43:00
User entered 'solumedrol'	Kimberly Mueller (b) (4)	08 Jan 2021 14:42:42

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:16
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4) Kimberly Mueller (b) (4) (b) (4)	08 Jan 2021 14:42:42

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:16
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'hydrocephalus'	(b) (4) Kimberly Mueller (b) (4) (b) (4)	08 Jan 2021 14:42:42

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:16
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '500'	(b) (4) Kimberly Mueller (b) (4) (b) (4)	08 Jan 2021 14:42:42

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:16
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'mg (mg)'	(b) (4) Kimberly Mueller (b) (4) (b) (4)	08 Jan 2021 14:42:42

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:16
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Kimberly Mueller (b) (4)	08 Jan 2021 14:42:42

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:16
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'once daily (QD)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:42:42

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:16
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	(b) (4) Kimberly Mueller (b) (4) (b) (4)	08 Jan 2021 14:42:42

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:16
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'Intravenous (INTRAVENOUS)'	Kimberly Mueller (b) (4)	08 Jan 2021 14:42:42

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:16
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered empty.	Kimberly Mueller (b) (4)	08 Jan 2021 14:42:42

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:16
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '10 Dec 2020'	(b) (4) Kimberly Mueller (b) (4) (b) (4)	08 Jan 2021 14:42:42

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:16
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '0'	(b) (4) Kimberly Mueller (b) (4) (b) (4)	08 Jan 2021 14:42:42

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:16
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4) Kimberly Mueller (b) (4) (b) (4)	08 Jan 2021 14:42:42

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:16
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '14 Dec 2020'	(b) (4) Kimberly Mueller (b) (4) (b) (4)	08 Jan 2021 14:42:42

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:16
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered 'No (N)'	(b) (4) Kimberly Mueller (b) (4) (b) (4)	08 Jan 2021 14:42:42

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:16
User entered '1'	System	08 Jan 2021 14:42:42

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:16
User entered '1'	System	08 Jan 2021 14:42:42

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:13:16
User entered '804 (804)'	System	08 Jan 2021 14:42:42

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:02
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Mar 2021 21:21:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 21:21:09
Data point term sent to Coder	System	30 Mar 2021 21:20:18
User entered 'Amlodipine'	(b) (4), (b) (6)	30 Mar 2021 21:19:57

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:02
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:19:57

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:02
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered 'Worsening of hypertension'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:19:57

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:02
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered '5'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:19:57

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:02
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:19:57

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:02
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:19:57

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:02
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:19:57

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:02
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:19:57

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:02
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:19:57

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:02
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:19:57

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:02
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:19:57

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:02
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:19:57

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:02
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 12:36:32
User signature succeeded.	Brandon Essink (b) (4)	14 Apr 2021 19:58:12
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 19:02:36
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 19:02:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 19:02:18
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 12:32:18
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 21:19:57

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:02
User signature succeeded.	Brandon Essink (b) (4)	14 Apr 2021 19:58:12
Signature has been broken.	(b) (4)	14 Apr 2021 19:02:18
User entered '17 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 19:02:18
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered empty.	(b) (4)	30 Mar 2021 21:19:57

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:02
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:19:57

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:02
User entered '1'	System	30 Mar 2021 21:19:57

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:02
User entered '1'	System	30 Mar 2021 21:19:57

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:02
User entered '804 (804)'	System	30 Mar 2021 21:19:57

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:06
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 21:22:11
Data point term sent to Coder	(b) (4)	
User entered 'Shingles vaccination'	System	30 Mar 2021 21:21:22
	(b) (4), (b) (6)	30 Mar 2021 21:20:30

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:06
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 21:20:30

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:06
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered 'Shingles prevention'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:30

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:06
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered '0.5'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:30

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:06
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:30

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:06
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:30

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:06
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:30

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:06
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:30

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:06
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:30

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:06
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:30

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:06
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:30

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:06
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:30

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:06
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:30

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:06
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:30

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:06
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:36:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Mar 2021 21:20:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Mar 2021 21:20:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 21:20:33
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Mar 2021 21:20:30
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 21:20:30

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:06
User entered empty.	System	30 Mar 2021 21:20:30

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:06
User entered empty.	System	30 Mar 2021 21:20:30

US3002259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:06
User entered empty.	System	30 Mar 2021 21:20:30

US3002259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:51:34

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:58:25
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:24:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 15:27:18
User closed query 'Per ETRTR, According to SAE hydrocephalus, Concomitant procedures box is checked. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 15:27:14
Query 'Per ETRTR, According to SAE hydrocephalus, Concomitant procedures box is checked. Please reconcile.' answered with 'done' (Site from CRA).	Kimberly Mueller (b) (4)	04 Feb 2021 14:22:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Kimberly Mueller (b) (4)	04 Feb 2021 14:22:09
User opened query 'Per ETRTR, According to SAE hydrocephalus, Concomitant procedures box is checked. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 17:30:00
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 17:58:56

US3002259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:51:34

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '15 Dec 2020'	Kimberly Mueller (b) (4)	04 Feb 2021 14:23:01
	(b) (4)	

US3002259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:51:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Ventriculoperitoneal shunt placement'	Kimberly Mueller (b) (4)	04 Feb 2021 14:23:01
	(b) (4)	

US3002259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:51:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered 'Adverse Event (AE)'	Kimberly Mueller (b) (4)	04 Feb 2021 14:23:01
	(b) (4)	

US3002259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:51:34

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered empty.	Kimberly Mueller (b) (4)	04 Feb 2021 14:23:01
	(b) (4)	

US3002259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:51:34

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:55:57
User signature succeeded.	Brandon Essink (b) (4)	18 Mar 2021 20:01:30
User entered '15 Dec 2020'	Kimberly Mueller (b) (4)	16 Mar 2021 23:35:48

US3002259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:51:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:55:57
User signature succeeded.	Brandon Essink (b) (4)	18 Mar 2021 20:01:30
User entered 'foley catheter placement'	Kimberly Mueller (b) (4)	16 Mar 2021 23:35:48

US3002259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:51:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:55:57
User signature succeeded.	Brandon Essink (b) (4)	18 Mar 2021 20:01:30
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	(b) (4)	16 Mar 2021 23:35:55
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	16 Mar 2021 23:35:48
User entered 'Adverse Event (AE)'	Kimberly Mueller (b) (4)	16 Mar 2021 23:35:48
	(b) (4)	

US3002259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:51:34

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:55:57
User signature succeeded.	Brandon Essink (b) (4)	18 Mar 2021 20:01:30
User entered empty; reason for change Data Entry Error	(b) (4)	
	Kimberly Mueller (b) (4)	16 Mar 2021 23:35:55
	(b) (4)	
User entered 'foley catheter removed 27Dec2020'	Kimberly Mueller (b) (4)	16 Mar 2021 23:35:48
	(b) (4)	

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'USA-US005-2020-MRNA-1273-P301000011'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Yes (Y)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Yes (Y)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Brandon'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Essink'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered '3319 N 107th'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Omaha'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered '68134'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:11:16
User entered 'US'	System	09 Dec 2020 18:26:51

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '6'	System	08 Jan 2021 15:15:38
User entered '5'	System	08 Jan 2021 14:46:07
User entered '4'	System	07 Jan 2021 15:39:54
User entered '3'	System	11 Dec 2020 20:38:35
User entered '2'	System	09 Dec 2020 21:11:24
User entered '1'	System	09 Dec 2020 18:26:51

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'USA-US005-2020-MRNA-1273-P301000011'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Yes (Y)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Yes (Y)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Brandon'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Essink'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered '3319 N 107th'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Omaha'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered '68134'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:11:16
User entered 'US'	System	09 Dec 2020 18:26:51

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '6'	System	08 Jan 2021 15:15:38
User entered '5'	System	08 Jan 2021 14:46:07
User entered '4'	System	07 Jan 2021 15:39:54
User entered '3'	System	11 Dec 2020 20:38:35
User entered '2'	System	09 Dec 2020 21:11:24
User entered '1'	System	09 Dec 2020 18:26:51

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:51:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '09/Dec/2020 18:26'	(b) (4) System	09 Dec 2020 18:26:51

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:51:34

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 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:11:16
User entered 'I'	(b) (4), (b) (6)	09 Dec 2020 18:26:51

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'USA-US005-2020-MRNA-1273-P301000011'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Yes (Y)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Yes (Y)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Brandon'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Essink'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered '3319 N 107th'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Omaha'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered '68134'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:11:16
User entered 'US'	System	09 Dec 2020 18:26:51

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '6'	System	08 Jan 2021 15:15:38
User entered '5'	System	08 Jan 2021 14:46:07
User entered '4'	System	07 Jan 2021 15:39:54
User entered '3'	System	11 Dec 2020 20:38:35
User entered '2'	System	09 Dec 2020 21:11:24
User entered '1'	System	09 Dec 2020 18:26:51

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:51:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '09/Dec/2020 21:11'	(b) (4) System	09 Dec 2020 21:11:24

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:51:34

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 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:39:45
User entered 'I'	(b) (4), (b) (6)	09 Dec 2020 21:11:24

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'USA-US005-2020-MRNA-1273-P301000011'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Yes (Y)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Yes (Y)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Brandon'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Essink'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered '3319 N 107th'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Omaha'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered '68134'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:11:16
User entered 'US'	System	09 Dec 2020 18:26:51

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '6'	System	08 Jan 2021 15:15:38
User entered '5'	System	08 Jan 2021 14:46:07
User entered '4'	System	07 Jan 2021 15:39:54
User entered '3'	System	11 Dec 2020 20:38:35
User entered '2'	System	09 Dec 2020 21:11:24
User entered '1'	System	09 Dec 2020 18:26:51

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:51:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '11/Dec/2020 15:38'	(b) (4) System	11 Dec 2020 20:38:35

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:51:34

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 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:39:45
User entered 'I'	(b) (4), (b) (6)	11 Dec 2020 20:38:35

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'USA-US005-2020-MRNA-1273-P301000011'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Yes (Y)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Yes (Y)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Brandon'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Essink'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered '3319 N 107th'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Omaha'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered '68134'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:11:16
User entered 'US'	System	09 Dec 2020 18:26:51

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '6'	System	08 Jan 2021 15:15:38
User entered '5'	System	08 Jan 2021 14:46:07
User entered '4'	System	07 Jan 2021 15:39:54
User entered '3'	System	11 Dec 2020 20:38:35
User entered '2'	System	09 Dec 2020 21:11:24
User entered '1'	System	09 Dec 2020 18:26:51

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:51:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '07/Jan/2021 15:39'	(b) (4) System	07 Jan 2021 15:39:54

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:51:34

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 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:06:14
User entered 'I'	(b) (4), (b) (6)	07 Jan 2021 15:39:54

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'USA-US005-2020-MRNA-1273-P301000011'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Yes (Y)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Yes (Y)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Brandon'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Essink'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered '3319 N 107th'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Omaha'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered '68134'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:11:16
User entered 'US'	System	09 Dec 2020 18:26:51

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '6'	System	08 Jan 2021 15:15:38
User entered '5'	System	08 Jan 2021 14:46:07
User entered '4'	System	07 Jan 2021 15:39:54
User entered '3'	System	11 Dec 2020 20:38:35
User entered '2'	System	09 Dec 2020 21:11:24
User entered '1'	System	09 Dec 2020 18:26:51

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:51:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '08/Jan/2021 09:46'	(b) (4) System	08 Jan 2021 14:46:07

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:51:34

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 12:36:34
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 15:06:14
User entered 'I'	(b) (4), (b) (6)	08 Jan 2021 14:46:07

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'USA-US005-2020-MRNA-1273-P301000011'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Yes (Y)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Yes (Y)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'No (N)'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Brandon'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Essink'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered '3319 N 107th'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered 'Omaha'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:46
User entered '68134'	System	09 Dec 2020 18:26:21

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:11:16
User entered 'US'	System	09 Dec 2020 18:26:51

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
	(b) (4)	
User entered '6'	System	08 Jan 2021 15:15:38
User entered '5'	System	08 Jan 2021 14:46:07
User entered '4'	System	07 Jan 2021 15:39:54
User entered '3'	System	11 Dec 2020 20:38:35
User entered '2'	System	09 Dec 2020 21:11:24
User entered '1'	System	09 Dec 2020 18:26:51

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:51:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 12:36:34
User entered '08/Jan/2021 15:15'	(b) (4) System	08 Jan 2021 15:15:38

US3002259

Folder: SAE USA-US005-2020-MRNA-1273-P301000011

Form: Safety Report Form (6)

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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 12:36:34
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:15:38