

US3902060 (Prod: Synexus - Optimal Research - Melbourne)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3902060

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Participant ID

US3902060

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

US3902060

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Date of Birth (MMM yyyy)	(b) (6) 1959
Age	61
Age Units	YEARS
Age (Derived)	61
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input 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) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Date of Informed Consent (<i>dd MMM yyyy</i>)	10 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) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN AUG 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)	AUG 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

Condition	HYPERCHOLESTEROLEMIA
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 (3)

Data signed: (b) (4) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

Condition	HYPERTRIGLYCERIDEMIA
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 (4)

Data signed: (b) (4) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

Condition	DIABETES
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

Condition	GASTRIC REFLUX
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

Condition	ENVIRONMENTAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:35 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 09:35
Height (<i>xxx.x</i>)	66 in
Weight (<i>xxx.x</i>)	176 lb
BMI (<i>xxx.x</i>)	28.46654 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) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 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) 19 Feb 2021 22:04:15

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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

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 22:04:15

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

What was the date of randomization? (dd MMM yyyy) 10 SEP 2020

What was the participant's randomization number? 145450

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) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

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) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

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)	10 SEP 2020
Time of assessment (00:00-23:59)	09:35 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 09:35
Temperature (xxx.x)	96.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 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: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	12:50 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 12:50
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	16 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 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: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

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) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

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) 10 SEP 2020

What was the treatment time? (00:00-23:59) 12:12 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 12:12

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) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	10 SEP 2020
Collection time (<i>00:00-23:59</i>)	11:24 (24 HR)
Collection date and time (derived)	10 SEP 2020 11:24

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:26	10 SEP 2020 11:26
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

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: 10 Jun 2021 10:19:01

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

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

10 SEP 2020 12:59

PC Open Date & Time

10 SEP 2020 12:32

PC Close Date & Time

10 SEP 2020 15:02

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.7 °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	11 SEP 2020 06:44
PC Open Date & Time	10 SEP 2020 15:57
PC Close Date & Time	11 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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 08:42

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 07:06

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 08:07

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:01

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:01

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 06:43

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:01

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

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

10 SEP 2020 12:59

PC Open Date & Time

10 SEP 2020 12:32

PC Close Date & Time

10 SEP 2020 15:02

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

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

11 SEP 2020 06:46

PC Open Date & Time

10 SEP 2020 15:57

PC Close Date & Time

11 SEP 2020 11:59

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:01

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

12 SEP 2020 08:43

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:01

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

13 SEP 2020 07:07

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:01

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

14 SEP 2020 08:07

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:01

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:01

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

16 SEP 2020 06:44

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:01

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

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 ☐

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 13:00
PC Open Date & Time	10 SEP 2020 12:32
PC Close Date & Time	10 SEP 2020 15:02

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

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 ☐

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 06:46
PC Open Date & Time	10 SEP 2020 15:57
PC Close Date & Time	11 SEP 2020 11:59

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:01

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 ☒

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:01

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 08:44
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:01

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 ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:01

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 07:08
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:01

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)

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Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:01

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 08:08
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:01

Yes ☐

PC Time stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:01

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
EAB) (1725)

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US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:01

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 06:45
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:01

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
EAB) (1725)

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US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:01

Yes ☐

PC Time stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3902060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3902060

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3902060

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3902060

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	09:19 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 09:19
Temperature (<i>xxx.x</i>)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	78 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

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)	14 OCT 2020
Time of assessment (00:00-23:59)	11:55 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 11:55
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	64 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

US3902060

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

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.

US3902060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

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) 14 OCT 2020

What was the treatment time? (00:00-23:59) 11:20 (24 HR)

Treatment Date and Time (derived) 14 OCT 2020 11:20

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

US3902060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 OCT 2020

Collection time (00:00-23:59)

10:40 (24 HR)

Collection date and time (derived)

14 OCT 2020 10:40

US3902060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

Collection date (<i>dd MMM yyyy</i>)			14 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:42	14 OCT 2020 10:42
Nasopharyngeal Swab 2	Yes	10:42	14 OCT 2020 10:42

US3902060

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 11:53

PC Open Date & Time

14 OCT 2020 11:40

PC Close Date & Time

14 OCT 2020 14:10

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.7 °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	14 OCT 2020 20:44
PC Open Date & Time	14 OCT 2020 15:05
PC Close Date & Time	15 OCT 2020 11:59

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:01

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

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	15 OCT 2020 20:02
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 20:59

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

17 OCT 2020 22:19

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

18 OCT 2020 20:42

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:01

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

97.7 °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

20 OCT 2020 02:39

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:01

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

97.7 °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

21 OCT 2020 03:18

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

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

14 OCT 2020 11:54

PC Open Date & Time

14 OCT 2020 11:40

PC Close Date & Time

14 OCT 2020 14:10

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 OCT 2020 20:45

PC Open Date & Time

14 OCT 2020 15:05

PC Close Date & Time

15 OCT 2020 11:59

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 OCT 2020 20:03

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:01

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

16 OCT 2020 21:00

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:01

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

17 OCT 2020 22:20

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:01

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

18 OCT 2020 20:43

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 OCT 2020 02:39

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 OCT 2020 03:18

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

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 ☐

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

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

No ☒

Yes ☐

PC Time stamp	14 OCT 2020 11:55
PC Open Date & Time	14 OCT 2020 11:40
PC Close Date & Time	14 OCT 2020 14:10

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

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 ☐

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

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

No ☒

Yes ☐

PC Time stamp	14 OCT 2020 20:45
PC Open Date & Time	14 OCT 2020 15:05
PC Close Date & Time	15 OCT 2020 11:59

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:01

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)

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:01

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 20:04
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:01

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 ☒

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EAB) (1725)

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US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:01

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 21:01
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:01

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 22:21
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:01

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 20:44
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:01

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

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EAB) (1725)

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:01

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 02:39
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:01

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 ☒

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:01

Yes <input type="checkbox"/>	
PC Time stamp	21 OCT 2020 03:19
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3902060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3902060

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3902060

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 7 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3902060

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

US3902060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	07:35 (24 HR)
Vital Signs Date and Time (derived)	10 NOV 2020 07:35
Temperature (<i>xxx.x</i>)	96.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	70 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	157 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3902060

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

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.

US3902060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	10 NOV 2020
Collection time (<i>00:00-23:59</i>)	07:55 (24 HR)
Collection date and time (derived)	10 NOV 2020 07:55

US3902060

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:04:15

Generated On: 10 Jun 2021 10:19:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

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

Date and time of submission

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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 <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"/>

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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)	<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"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

09 DEC 2020 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 20:04:15
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 JAN 2021 18:17:52

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 06:48:28

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

26 JAN 2021 07:09:50

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 FEB 2021 12:00:38

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

08 FEB 2021 12:02:58

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

17 FEB 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

24 FEB 2021 10:42:13

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 173

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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 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"/>
Date and time of submission	07 MAR 2021 15:42:52
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

24 MAR 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

31 MAR 2021 08:34:28

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

05 APR 2021 12:00:40

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

11 APR 2021 12:49:05

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

17 APR 2021 07:39:38

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

26 APR 2021 12:00:52

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 236

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

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

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

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

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

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

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

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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 ☐

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 271

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01
Patient Cloud Close Date & Time	09 JUN 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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 ☐

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01
Patient Cloud Close Date & Time	30 JUN 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	07 JUL 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
Patient Cloud Close Date & Time	18 AUG 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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 ☐

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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 ☐

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	29 SEP 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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 ☐

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	27 OCT 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

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 ☐

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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 ☐

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 481

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

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

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

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

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

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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 ☐

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
Patient Cloud Close Date & Time	16 FEB 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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 ☐

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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 ☐

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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 ☐

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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 ☐

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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 ☐

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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 ☐

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	06 APR 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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 ☐

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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 ☐

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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="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"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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 ☐

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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 ☐

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2022 00:01
Patient Cloud Close Date & Time	29 JUN 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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 ☐

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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 ☐

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	20 JUL 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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 ☐

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
Patient Cloud Close Date & Time	24 AUG 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	12 OCT 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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 ☐

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	26 OCT 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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"/>

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2022 00:01
Patient Cloud Close Date & Time	16 NOV 2022 23:59

US3902060

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:19:01

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		04 MAR 2021 04:07:31

US3902060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3902060

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3902060

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902060

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:36:56

Generated On: 10 Jun 2021 10:19:01

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3902060

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:36:56

Generated On: 10 Jun 2021 10:19:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902060

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 16:42:10

Generated On: 10 Jun 2021 10:19:01

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3902060

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:42:10

Generated On: 10 Jun 2021 10:19:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902060

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 16:44:40

Generated On: 10 Jun 2021 10:19:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 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

US3902060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 16:44:40

Generated On: 10 Jun 2021 10:19:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	31 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	07:52 (24 HR)
Vital Signs Date and Time (derived)	31 MAR 2021 07:52
Temperature (<i>xxx.x</i>)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3902060

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 16:42:10

Generated On: 10 Jun 2021 10:19:01

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.

US3902060

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 16:42:10

Generated On: 10 Jun 2021 10:19:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	31 MAR 2021
Collection time (00:00-23:59)	08:32 (24 HR)
Collection date and time (derived)	31 MAR 2021 08:32

US3902060

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:42:10

Generated On: 10 Jun 2021 10:19:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902060

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

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

US3902060

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3902060

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:19:01

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"/>

US3902060

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:19:01

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3902060

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 16:42:10

Generated On: 10 Jun 2021 10:19:01

Date of updated informed consent (*dd MMM yyyy*) 9 FEB 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒
No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐
Amendment 6 or later ☒

Date of unblinding (*dd MMM yyyy*) 9 FEB 2021

Participant randomization assignment mRNA-1273 ☒
Placebo ☐

Actual Dose 1 mRNA-1273 ☒
Placebo ☐
Not Administered ☐

Actual Dose 2 mRNA-1273 ☒
Placebo ☐
Not Administered ☐

Will participant receive mRNA-1273? Yes ☐
No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3902060

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 FEB 2021
Collection time (00:00-23:59)	10:47 (24 HR)
Collection date and time (derived)	9 FEB 2021 10:47

US3902060

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 FEB 2021
Collection time (00:00 - 23:59)	10:45
Collection Date and Time (derived)	9 FEB 2021 10:45

US3902060

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

AEID

Adverse event

RIGHT EARACHE

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)

27 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy)

30 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐
Grade 2/Moderate ☒
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious?

Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

AEID	USA-US210-2021-MRNA-1273-P30 1000003
Adverse event	PANCREATITIS
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)	2 MAR 2021
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 type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input 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)	2 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

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	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

SUBJECT CONTACTED BY SITE
STAFF ON 08MAR2021 AND
STATED HE IS IN THE
HOSPITAL WITH
PANCREATITIS. STATES HE
HAD ABDOMINAL PAIN ON
02MAR2021 AND WAS
ADMITTED FOR WORK UP.
SUBJECT STATES HE IS
FEELING BETTER AND
ANTICIPATED DISCHARGE
TOMORROW ON 09MAR2021.
SUBJECT SAYS HE FORGOT TO
NOTIFY SITE. SENT SUBJECT
MEDICAL RELEASE FORM TO
HOME.

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

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Name of Medication LORATADINE

Prophylaxis Yes ☐
No ☒

Indication ENVIRONMENTAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

	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 2016	
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 (2)

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES

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 (2)

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

	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 2012	
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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Name of Medication LOSARTAN

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 (3)

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN AUG 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTRIC REFLUX

Dose per administration 40

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) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

	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 2012	
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) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

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 (5)

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

	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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Name of Medication FENOFIBRATE

Prophylaxis Yes ☐
No ☒

Indication HYPERTRIGLYCERIDEMIA

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

	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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication MYALGIA

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

	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)		15 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

Name of Medication ERYTHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication RIGHT EARACHE

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Feb 2021 22:04:14

Generated On: 10 Jun 2021 10:19:01

	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)	27 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 OCT 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"/>

US3902060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 17:36:56

Generated On: 10 Jun 2021 10:19:01

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3902060

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:19:01

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

US3902060

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:19:01

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 ☐

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 20:44:27

Generated On: 10 Jun 2021 10:19:01

SAEID	USA-US210-2021-MRNA-1273-P301000003
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	MURRAY
Investigator's Last Name	KIMMEL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 20:44:27

Generated On: 10 Jun 2021 10:19:01

SAEID	USA-US210-2021-MRNA-1273-P301000003
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	MURRAY
Investigator's Last Name	KIMMEL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	09/MAR/2021 07:37
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

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 20:44:27

Generated On: 10 Jun 2021 10:19:01

SAEID	USA-US210-2021-MRNA-1273-P301000003
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	MURRAY
Investigator's Last Name	KIMMEL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	12/APR/2021 17:52
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3902060 (Prod: Synexus - Optimal Research - Melbourne)

US3902060

Form: Participant Creation

Generated On: 10 Jun 2021 10:19:01

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'US3902060'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 13:49:42

US3902060

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:19:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	10 Sep 2020 16:25:30
	(b) (4)	

US3902060

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '10 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 13:49:43

US3902060

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Clinic (Clinic)'	Taylor Atkinson (b) (4)	10 Sep 2020 16:25:30
	(b) (4)	

US3902060

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:19:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered 'SCRN'	System	10 Sep 2020 16:25:30

US3902060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:01

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered (b) (6) 1959'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 13:49:44

US3902060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:01

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '61'	Taylor Atkinson (b) (4)	10 Sep 2020 16:25:53
	(b) (4)	

US3902060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:01

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered 'YEARS'	System	10 Sep 2020 16:25:53

US3902060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:01

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered '61'	System	10 Sep 2020 16:31:55

US3902060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:01

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Male (M)'	Taylor Atkinson (b) (4)	10 Sep 2020 16:25:53
	(b) (4)	

US3902060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:01

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Taylor Atkinson (b) (4)	10 Sep 2020 16:25:53
	(b) (4)	

US3902060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:01

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'I'	Taylor Atkinson (b) (4)	10 Sep 2020 16:25:53
	(b) (4)	

US3902060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:01

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Taylor Atkinson (b) (4)	10 Sep 2020 16:25:53
	(b) (4)	

US3902060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:01

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Taylor Atkinson (b) (4)	10 Sep 2020 16:25:53
	(b) (4)	

US3902060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:01

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Taylor Atkinson (b) (4)	10 Sep 2020 16:25:53
	(b) (4)	

US3902060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:01

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Taylor Atkinson (b) (4)	10 Sep 2020 16:25:53
	(b) (4)	

US3902060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:01

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Taylor Atkinson (b) (4)	10 Sep 2020 16:25:53
	(b) (4)	

US3902060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:01

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Taylor Atkinson (b) (4)	10 Sep 2020 16:25:53
	(b) (4)	

US3902060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:01

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Taylor Atkinson (b) (4)	10 Sep 2020 16:25:53
	(b) (4)	

US3902060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:01

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Taylor Atkinson (b) (4)	10 Sep 2020 16:25:53
	(b) (4)	

US3902060

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:19:01

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '10 Sep 2020'	Taylor Atkinson (b) (4)	10 Sep 2020 16:31:55
	(b) (4)	

US3902060

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered 'Sep 2020'	System	10 Sep 2020 16:31:55

US3902060

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered '2020'	System	10 Sep 2020 16:31:55

US3902060

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:19:01

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Amendment 3 (3)'	Taylor Atkinson (b) (4)	10 Sep 2020 16:31:55
	(b) (4)	

US3902060

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	10 Sep 2020 16:31:55
	(b) (4)	

US3902060

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:19:01

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Taylor Atkinson (b) (4)	10 Sep 2020 16:31:55
	(b) (4)	

US3902060

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:19:01

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Taylor Atkinson (b) (4)	10 Sep 2020 16:31:55
	(b) (4)	

US3902060

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:19:01

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Taylor Atkinson (b) (4)	10 Sep 2020 16:31:55
	(b) (4)	

US3902060

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:19:01

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 13:49:43

US3902060

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:19:01

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered '1'	System	10 Sep 2020 16:32:09

US3902060

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	10 Sep 2020 16:32:09
	(b) (4)	

US3902060

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:19:01

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	18 Sep 2020 19:06:07

US3902060

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
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)	18 Sep 2020 19:07:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 19:07:43
	(b) (4)	
Data point term sent to Coder	System	18 Sep 2020 19:06:49
User entered 'hypertension'	Bram Swarr (b) (4)	18 Sep 2020 19:06:31

US3902060

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'un Aug 2019'	Bram Swarr (b) (4)	18 Sep 2020 19:06:31

US3902060

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	18 Sep 2020 19:06:31

US3902060

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	18 Sep 2020 19:06:31

US3902060

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	18 Sep 2020 19:06:31

US3902060

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	18 Sep 2020 19:06:31

US3902060

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered 'Aug 2019'	System	18 Sep 2020 19:06:31

US3902060

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered '2019'	System	18 Sep 2020 19:06:31

US3902060

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered empty.	System	18 Sep 2020 19:06:31

US3902060

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered empty.	System	18 Sep 2020 19:06:31

US3902060

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:19:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 19:07:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 19:07:43
	(b) (4)	
Data point term sent to Coder	System	18 Sep 2020 19:06:49
User entered 'hypercholesterolemia'	Bram Swarr (b) (4)	18 Sep 2020 19:06:46

US3902060

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'un UNK 2015'	Bram Swarr (b) (4)	18 Sep 2020 19:06:46

US3902060

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:19:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	18 Sep 2020 19:06:46

US3902060

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:19:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	18 Sep 2020 19:06:46

US3902060

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:19:01

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	18 Sep 2020 19:06:46

US3902060

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:19:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	18 Sep 2020 19:06:46

US3902060

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered 'Jan 2015'	System	18 Sep 2020 19:06:46

US3902060

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered '2015'	System	18 Sep 2020 19:06:46

US3902060

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered empty.	System	18 Sep 2020 19:06:46

US3902060

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered empty.	System	18 Sep 2020 19:06:46

US3902060

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:19:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated triglycerides, PT: Hypertriglyceridaemia, LLT: Hypertriglyceridemia - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 19:08:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 19:08:34
	(b) (4)	
Data point term sent to Coder	System	18 Sep 2020 19:07:50
User entered 'hypertriglyceridemia'	Bram Swarr (b) (4)	18 Sep 2020 19:07:48

US3902060

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'un UNK 2015'	Bram Swarr (b) (4)	18 Sep 2020 19:07:48

US3902060

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:19:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	18 Sep 2020 19:07:48

US3902060

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:19:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	18 Sep 2020 19:07:48

US3902060

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	18 Sep 2020 19:07:48

US3902060

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:19:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	18 Sep 2020 19:07:48

US3902060

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered 'Jan 2015'	System	18 Sep 2020 19:07:48

US3902060

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:19:01

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered '2015'	System	18 Sep 2020 19:07:48

US3902060

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered empty.	System	18 Sep 2020 19:07:48

US3902060

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered empty.	System	18 Sep 2020 19:07:48

US3902060

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:19:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 19:09:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 19:09:34
	(b) (4)	
Data point term sent to Coder	System	18 Sep 2020 19:08:51
User entered 'diabetes'	Bram Swarr (b) (4)	18 Sep 2020 19:08:08

US3902060

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'un UNK 2010'	Bram Swarr (b) (4)	18 Sep 2020 19:08:08

US3902060

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:19:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	18 Sep 2020 19:08:08

US3902060

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:19:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	18 Sep 2020 19:08:08

US3902060

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	18 Sep 2020 19:08:08

US3902060

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:19:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	18 Sep 2020 19:08:08

US3902060

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered 'Jan 2010'	System	18 Sep 2020 19:08:08

US3902060

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered '2010'	System	18 Sep 2020 19:08:08

US3902060

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered empty.	System	18 Sep 2020 19:08:08

US3902060

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered empty.	System	18 Sep 2020 19:08:08

US3902060

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:19:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 19:09:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 19:09:35
	(b) (4)	
Data point term sent to Coder	System	18 Sep 2020 19:08:51
User entered 'gastric reflux'	Bram Swarr (b) (4)	18 Sep 2020 19:08:24

US3902060

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'un UNK 2012'	Bram Swarr (b) (4)	18 Sep 2020 19:08:24

US3902060

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:19:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	18 Sep 2020 19:08:24

US3902060

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:19:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	18 Sep 2020 19:08:24

US3902060

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:19:01

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	18 Sep 2020 19:08:24

US3902060

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:19:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	18 Sep 2020 19:08:24

US3902060

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered 'Jan 2012'	System	18 Sep 2020 19:08:24

US3902060

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered '2012'	System	18 Sep 2020 19:08:24

US3902060

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered empty.	System	18 Sep 2020 19:08:24

US3902060

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered empty.	System	18 Sep 2020 19:08:24

US3902060

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:19:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 19:09:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 19:09:35
	(b) (4)	
Data point term sent to Coder	System	18 Sep 2020 19:08:53
User entered 'environmental allergies'	Bram Swarr (b) (4)	18 Sep 2020 19:08:37

US3902060

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'un UNK 2016'	Bram Swarr (b) (4)	18 Sep 2020 19:08:37

US3902060

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:19:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	18 Sep 2020 19:08:37

US3902060

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:19:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	18 Sep 2020 19:08:37

US3902060

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:19:01

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	18 Sep 2020 19:08:37

US3902060

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:19:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	18 Sep 2020 19:08:37

US3902060

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered 'Jan 2016'	System	18 Sep 2020 19:08:37

US3902060

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered '2016'	System	18 Sep 2020 19:08:37

US3902060

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered empty.	System	18 Sep 2020 19:08:37

US3902060

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered empty.	System	18 Sep 2020 19:08:37

US3902060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	18 Sep 2020 19:05:53

US3902060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '10 Sep 2020'	Bram Swarr (b) (4)	18 Sep 2020 19:05:53

US3902060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '09:35'	Bram Swarr (b) (4)	18 Sep 2020 19:05:53

US3902060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered '10 Sep 2020 09:35'	System	18 Sep 2020 19:05:53

US3902060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '66' in	Bram Swarr (b) (4)	18 Sep 2020 19:05:53
DataPoint set to visible.	System	10 Sep 2020 16:32:09

US3902060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '176' lb	Bram Swarr (b) (4)	18 Sep 2020 19:05:53
DataPoint set to visible.	System	10 Sep 2020 16:32:09

US3902060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered '28.46654'	System	18 Sep 2020 19:05:53
DataPoint set to visible.	System	10 Sep 2020 16:32:09

US3902060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered 'kg/m2'	System	18 Sep 2020 19:05:53
DataPoint set to visible.	System	10 Sep 2020 16:32:09

US3902060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	18 Sep 2020 19:05:53

US3902060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	18 Sep 2020 19:05:53

US3902060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	18 Sep 2020 19:05:53

US3902060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	18 Sep 2020 19:05:53

US3902060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered 'bpm'	System	18 Sep 2020 19:05:53

US3902060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	18 Sep 2020 19:05:53

US3902060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered 'breaths/min'	System	18 Sep 2020 19:05:53

US3902060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	18 Sep 2020 19:05:53

US3902060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered 'mmHg'	System	18 Sep 2020 19:05:53

US3902060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	18 Sep 2020 19:05:53

US3902060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered 'mmHg'	System	18 Sep 2020 19:05:53

US3902060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 10:30:05

US3902060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05

US3902060

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:01

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	18 Sep 2020 19:08:54

US3902060

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '10 Sep 2020'	Bram Swarr (b) (4)	18 Sep 2020 19:08:54

US3902060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	18 Sep 2020 19:04:51

US3902060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	18 Sep 2020 19:04:51

US3902060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:01

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)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	18 Sep 2020 19:04:51

US3902060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:01

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)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	18 Sep 2020 19:04:51

US3902060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:01

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	18 Sep 2020 19:04:51

US3902060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:01

[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)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	18 Sep 2020 19:04:51

US3902060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:01

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)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	18 Sep 2020 19:04:51

US3902060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:01

[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)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	18 Sep 2020 19:04:51

US3902060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:01

[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)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	18 Sep 2020 19:04:51

US3902060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:01

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)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	18 Sep 2020 19:04:51

US3902060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:01

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)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	18 Sep 2020 19:04:51

US3902060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:01

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	18 Sep 2020 19:04:51

US3902060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:01

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	18 Sep 2020 19:04:51

US3902060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:01

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	18 Sep 2020 19:04:51

US3902060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	18 Sep 2020 19:04:51

US3902060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:01

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)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	18 Sep 2020 19:04:51

US3902060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:01

[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)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	18 Sep 2020 19:04:51

US3902060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:01

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)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	18 Sep 2020 19:04:51

US3902060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'I'	Bram Swarr (b) (4)	18 Sep 2020 19:04:51

US3902060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:01

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	18 Sep 2020 19:04:51

US3902060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:01

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	18 Sep 2020 19:04:51

US3902060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:19:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	18 Sep 2020 19:10:02

US3902060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '10 Sep 2020'	Bram Swarr (b) (4)	18 Sep 2020 19:10:02

US3902060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Clinic (Clinic)'	Bram Swarr (b) (4)	18 Sep 2020 19:10:02

US3902060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:19:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'VISIT1'	System	18 Sep 2020 19:10:02

US3902060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '10 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 15:19:31

US3902060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:19:01

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '145450'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 15:19:31

US3902060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:19:01

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 15:19:31

US3902060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:19:01

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)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	18 Sep 2020 19:11:08

US3902060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:19:01

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)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	18 Sep 2020 19:11:08

US3902060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:19:01

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	18 Sep 2020 19:11:08

US3902060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:19:01

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	18 Sep 2020 19:11:08

US3902060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:19:01

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	18 Sep 2020 19:11:08

US3902060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:19:01

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 12:19:10
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'updated' (Site from DM).	Taylor Atkinson (b) (4)	12 Dec 2020 14:14:12
User entered 'No (N)'	Taylor Atkinson (b) (4)	12 Dec 2020 14:14:06
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 05:45:07
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:56:49
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:56:48

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:19:01

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:19:01

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:19:01

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:19:01

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User accepted default value 'Pre-Dose (PREDOSE)'	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '10 Sep 2020'	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '09:35'	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered '10 Sep 2020 09:35'	System	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 06:06:02
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs per PI, no AE needed' (Site from System).	Bram Swarr (b) (4)	18 Sep 2020 19:15:17
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	18 Sep 2020 19:14:44
User entered '96.1' F	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Oral (Oral)'	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '73'	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'bpm'	System	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '16'	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'breaths/min'	System	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User closed query 'Per CDM: Per CCG V2.0 page 50, SBP \leq 89 or \geq 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:41:37
Query 'Per CDM: Per CCG V2.0 page 50, SBP \leq 89 or \geq 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'As per PI, NCS' (Site from DM).	Taylor Atkinson (b) (4)	04 Nov 2020 13:10:25
User opened query 'Per CDM: Per CCG V2.0 page 50, SBP \leq 89 or \geq 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 10:22:34
User entered '145'	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'mmHg'	System	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '76'	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'mmHg'	System	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:19:01

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:19:01

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User accepted default value 'Post-Dose (POSTDOSE)'	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '10 Sep 2020'	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '12:50'	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered '10 Sep 2020 12:50'	System	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '97.5' F	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Oral (Oral)'	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 06:05:34
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs per PI, no AE needed' (Site from System).	Bram Swarr (b) (4)	18 Sep 2020 19:15:25
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	18 Sep 2020 19:14:44
User entered '16'	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'bpm'	System	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '16'	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'breaths/min'	System	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User closed query 'Per CDM: Per CCG V2.0 page 50, SBP \leq 89 or \geq 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:41:43
Query 'Per CDM: Per CCG V2.0 page 50, SBP \leq 89 or \geq 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'As per PI, NCS' (Site from DM).	Taylor Atkinson (b) (4)	04 Nov 2020 13:10:35
User opened query 'Per CDM: Per CCG V2.0 page 50, SBP \leq 89 or \geq 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 10:26:07
User entered '146'	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'mmHg'	System	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '85'	Bram Swarr (b) (4)	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'mmHg'	System	18 Sep 2020 19:14:44

US3902060

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	18 Sep 2020 19:10:08

US3902060

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:01

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	18 Sep 2020 19:10:08

US3902060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:19:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	10 Sep 2020 16:33:25

US3902060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:19:01

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Taylor Atkinson (b) (4)	10 Sep 2020 16:33:25

US3902060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:19:01

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)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Taylor Atkinson (b) (4)	10 Sep 2020 16:33:25

US3902060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:19:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 16:33:25

US3902060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:19:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '10 Sep 2020'	Taylor Atkinson (b) (4)	10 Sep 2020 16:33:25

US3902060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:19:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '12:12'	Taylor Atkinson (b) (4)	10 Sep 2020 16:33:25

US3902060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:19:01

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered '10 Sep 2020 12:12'	System	10 Sep 2020 16:33:25

US3902060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:19:01

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Left Arm (LEFT ARM)'	Taylor Atkinson (b) (4)	10 Sep 2020 16:33:25

US3902060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:19:01

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'ONCE'	System	10 Sep 2020 16:33:25

US3902060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:19:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 16:33:25

US3902060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	18 Sep 2020 19:16:52

US3902060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '10 Sep 2020'	Bram Swarr (b) (4)	18 Sep 2020 19:16:52

US3902060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:01

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '11:24'	Bram Swarr (b) (4)	18 Sep 2020 19:16:52

US3902060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered '10 Sep 2020 11:24'	System	18 Sep 2020 19:16:52

US3902060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:19:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '10 Sep 2020'	Bram Swarr (b) (4)	18 Sep 2020 19:17:14

US3902060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:19:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Bram Swarr (b) (4)	18 Sep 2020 19:17:14

US3902060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:19:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	18 Sep 2020 19:17:14

US3902060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:19:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '11:26'	Bram Swarr (b) (4)	18 Sep 2020 19:17:14

US3902060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered '10 Sep 2020 11:26'	System	18 Sep 2020 19:17:14

US3902060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:19:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Bram Swarr (b) (4)	18 Sep 2020 19:17:14

US3902060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:19:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	18 Sep 2020 19:17:14

US3902060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:19:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	18 Sep 2020 19:17:14

US3902060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered empty.	System	18 Sep 2020 19:17:14

US3902060

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	18 Sep 2020 19:17:33

US3902060

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered '1'	System	18 Sep 2020 19:17:33

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	10 Sep 2020 16:33:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-10T12:58:35', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '146f9760-a0d8-4c9f-82e7-ba6a8f889ea2'	System	10 Sep 2020 16:59:04
User entered 'Yes (Y)'	System	10 Sep 2020 16:59:04

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-10T12:58:46', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '146f9760-a0d8-4c9f-82e7-ba6a8f889ea2'	System	10 Sep 2020 16:59:04
User entered '97.5'	System	10 Sep 2020 16:59:04

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-10T12:58:52', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '146f9760-a0d8-4c9f-82e7-ba6a8f889ea2'	System	10 Sep 2020 16:59:04
User entered 'No (N)'	System	10 Sep 2020 16:59:04

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-10T12:59:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '146f9760-a0d8-4c9f-82e7-ba6a8f889ea2'	System	10 Sep 2020 16:59:04
User entered '10 Sep 2020 12:59'	System	10 Sep 2020 16:59:04

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '10 Sep 2020 12:32'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '10 Sep 2020 15:02'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	10 Sep 2020 16:33:25
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-11T06:43:59', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'bd8de563-811a-4e32-86a7-4237dc5bb1f0'	System	11 Sep 2020 10:44:26
User entered 'Yes (Y)'	System	11 Sep 2020 10:44:26

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-11T06:44:07', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'bd8de563-811a-4e32-86a7-4237dc5bb1f0'	System	11 Sep 2020 10:44:26
User entered '97.7'	System	11 Sep 2020 10:44:26

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-11T06:44:13', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'bd8de563-811a-4e32-86a7-4237dc5bb1f0'	System	11 Sep 2020 10:44:26
User entered 'No (N)'	System	11 Sep 2020 10:44:26

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-11T06:44:22', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'bd8de563-811a-4e32-86a7-4237dc5bb1f0'	System	11 Sep 2020 10:44:26
User entered '11 Sep 2020 06:44'	System	11 Sep 2020 10:44:26

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '10 Sep 2020 15:57'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	10 Sep 2020 16:33:25
User entered 'Day 2'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-12T08:42:04', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '3dcc5338-c500-4264-bc9b-6d958bb5c294'	System	12 Sep 2020 12:42:32
User entered 'Yes (Y)'	System	12 Sep 2020 12:42:32

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-12T08:42:19', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '3dcc5338-c500-4264-bc9b-6d958bb5c294'	System	12 Sep 2020 12:42:32
User entered '97.7'	System	12 Sep 2020 12:42:32

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-12T08:42:24', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '3dcc5338-c500-4264-bc9b-6d958bb5c294'	System	12 Sep 2020 12:42:32
User entered 'No (N)'	System	12 Sep 2020 12:42:32

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-12T08:42:30', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '3dcc5338-c500-4264-bc9b-6d958bb5c294'	System	12 Sep 2020 12:42:32
User entered '12 Sep 2020 08:42'	System	12 Sep 2020 12:42:32

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	10 Sep 2020 16:33:25
User entered 'Day 3'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-13T07:06:18', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '006542f6-ca18-4b26-8e24-27d095094193'	System	13 Sep 2020 11:06:45
User entered 'Yes (Y)'	System	13 Sep 2020 11:06:45

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-13T07:06:27', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '006542f6-ca18-4b26-8e24-27d095094193'	System	13 Sep 2020 11:06:45
User entered '97.2'	System	13 Sep 2020 11:06:45

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-13T07:06:36', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '006542f6-ca18-4b26-8e24-27d095094193'	System	13 Sep 2020 11:06:45
User entered 'No (N)'	System	13 Sep 2020 11:06:45

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-13T07:06:43', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '006542f6-ca18-4b26-8e24-27d095094193'	System	13 Sep 2020 11:06:45
User entered '13 Sep 2020 07:06'	System	13 Sep 2020 11:06:45

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	10 Sep 2020 16:33:25
User entered 'Day 4'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-14T08:06:54', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '667e11f7-da74-44be-84b8-995430178ea2'	System	14 Sep 2020 12:07:15
User entered 'Yes (Y)'	System	14 Sep 2020 12:07:15

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-14T08:07:03', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '667e11f7-da74-44be-84b8-995430178ea2'	System	14 Sep 2020 12:07:15
User entered '97.3'	System	14 Sep 2020 12:07:15

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-14T08:07:09', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '667e11f7-da74-44be-84b8-995430178ea2'	System	14 Sep 2020 12:07:15
User entered 'No (N)'	System	14 Sep 2020 12:07:15

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-14T08:07:13', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '667e11f7-da74-44be-84b8-995430178ea2'	System	14 Sep 2020 12:07:15
User entered '14 Sep 2020 08:07'	System	14 Sep 2020 12:07:15

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	10 Sep 2020 16:33:25
User entered 'Day 5'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	10 Sep 2020 16:33:25
User entered 'Day 6'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-16T06:43:30', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '26b0905e-3a34-4982-8fb5-3643a25c7b37'	System	16 Sep 2020 10:43:50
User entered 'Yes (Y)'	System	16 Sep 2020 10:43:50

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-16T06:43:38', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '26b0905e-3a34-4982-8fb5-3643a25c7b37'	System	16 Sep 2020 10:43:50
User entered '97.2'	System	16 Sep 2020 10:43:50

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-16T06:43:44', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '26b0905e-3a34-4982-8fb5-3643a25c7b37'	System	16 Sep 2020 10:43:50
User entered 'No (N)'	System	16 Sep 2020 10:43:50

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-16T06:43:47', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '26b0905e-3a34-4982-8fb5-3643a25c7b37'	System	16 Sep 2020 10:43:50
User entered '16 Sep 2020 06:43'	System	16 Sep 2020 10:43:50

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	10 Sep 2020 16:33:25
User entered 'Day 7'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	10 Sep 2020 16:33:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-10T12:59:10', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '61180fe8-6b52-446a-ab67-68c85a59d95c'	System	10 Sep 2020 16:59:42
User entered 'None (1)'	System	10 Sep 2020 16:59:42

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-10T12:59:15', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '61180fe8-6b52-446a-ab67-68c85a59d95c'	System	10 Sep 2020 16:59:42
User entered 'No (N)'	System	10 Sep 2020 16:59:42

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-10T12:59:19', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '61180fe8-6b52-446a-ab67-68c85a59d95c'	System	10 Sep 2020 16:59:42
User entered 'No (N)'	System	10 Sep 2020 16:59:42

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-10T12:59:29', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '61180fe8-6b52-446a-ab67-68c85a59d95c'	System	10 Sep 2020 16:59:42
User entered 'None (1)'	System	10 Sep 2020 16:59:42

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-10T12:59:40', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '61180fe8-6b52-446a-ab67-68c85a59d95c'	System	10 Sep 2020 16:59:42
User entered '10 Sep 2020 12:59'	System	10 Sep 2020 16:59:42

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '10 Sep 2020 12:32'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '10 Sep 2020 15:02'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	10 Sep 2020 16:33:25
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-11T06:45:05', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '2efd4f15-ee52-40da-bb98-9d142a3d1234'	System	11 Sep 2020 10:46:04
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 10:46:04

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-11T06:45:39', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '2efd4f15-ee52-40da-bb98-9d142a3d1234'	System	11 Sep 2020 10:46:04
User entered 'No (N)'	System	11 Sep 2020 10:46:04

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-11T06:45:44', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '2efd4f15-ee52-40da-bb98-9d142a3d1234'	System	11 Sep 2020 10:46:04
User entered 'No (N)'	System	11 Sep 2020 10:46:04

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-11T06:45:50', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '2efd4f15-ee52-40da-bb98-9d142a3d1234'	System	11 Sep 2020 10:46:04
User entered 'None (1)'	System	11 Sep 2020 10:46:04

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-11T06:46:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '2efd4f15-ee52-40da-bb98-9d142a3d1234'	System	11 Sep 2020 10:46:04
User entered '11 Sep 2020 06:46'	System	11 Sep 2020 10:46:04

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '10 Sep 2020 15:57'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	10 Sep 2020 16:33:25
User entered 'Day 2'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-12T08:42:38', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'c5db4d5b-e2db-42b0-bc4c-7b7e8bc568f4'	System	12 Sep 2020 12:43:05
User entered 'None (1)'	System	12 Sep 2020 12:43:05

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-12T08:42:41', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'c5db4d5b-e2db-42b0-bc4c-7b7e8bc568f4'	System	12 Sep 2020 12:43:05
User entered 'No (N)'	System	12 Sep 2020 12:43:05

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-12T08:42:58', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'c5db4d5b-e2db-42b0-bc4c-7b7e8bc568f4'	System	12 Sep 2020 12:43:05
User entered 'No (N)'	System	12 Sep 2020 12:43:05

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-12T08:42:51', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'c5db4d5b-e2db-42b0-bc4c-7b7e8bc568f4'	System	12 Sep 2020 12:43:05
User entered 'None (1)'	System	12 Sep 2020 12:43:05

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-12T08:43:02', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'c5db4d5b-e2db-42b0-bc4c-7b7e8bc568f4'	System	12 Sep 2020 12:43:05
User entered '12 Sep 2020 08:43'	System	12 Sep 2020 12:43:05

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	10 Sep 2020 16:33:25
User entered 'Day 3'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-13T07:06:53', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'a31868cc-dcc9-46e5-a86a-5aba6291a043'	System	13 Sep 2020 11:07:35
User entered 'None (1)'	System	13 Sep 2020 11:07:35

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-13T07:07:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'a31868cc-dcc9-46e5-a86a-5aba6291a043'	System	13 Sep 2020 11:07:35
User entered 'No (N)'	System	13 Sep 2020 11:07:35

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-13T07:07:04', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'a31868cc-dcc9-46e5-a86a-5aba6291a043'	System	13 Sep 2020 11:07:35
User entered 'No (N)'	System	13 Sep 2020 11:07:35

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-13T07:07:14', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'a31868cc-dcc9-46e5-a86a-5aba6291a043'	System	13 Sep 2020 11:07:35
User entered 'None (1)'	System	13 Sep 2020 11:07:35

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-13T07:07:32', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'a31868cc-dcc9-46e5-a86a-5aba6291a043'	System	13 Sep 2020 11:07:35
User entered '13 Sep 2020 07:07'	System	13 Sep 2020 11:07:35

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	10 Sep 2020 16:33:25
User entered 'Day 4'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-14T08:07:20', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'd6222d49-e6a2-435a-a9d5-e5dacd96846f'	System	14 Sep 2020 12:07:36
User entered 'None (1)'	System	14 Sep 2020 12:07:36

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-14T08:07:23', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'd6222d49-e6a2-435a-a9d5-e5dacd96846f'	System	14 Sep 2020 12:07:36
User entered 'No (N)'	System	14 Sep 2020 12:07:36

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-14T08:07:26', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'd6222d49-e6a2-435a-a9d5-e5dacd96846f'	System	14 Sep 2020 12:07:36
User entered 'No (N)'	System	14 Sep 2020 12:07:36

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-14T08:07:30', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'd6222d49-e6a2-435a-a9d5-e5dacd96846f'	System	14 Sep 2020 12:07:36
User entered 'None (1)'	System	14 Sep 2020 12:07:36

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-14T08:07:34', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'd6222d49-e6a2-435a-a9d5-e5dacd96846f'	System	14 Sep 2020 12:07:36
User entered '14 Sep 2020 08:07'	System	14 Sep 2020 12:07:36

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	10 Sep 2020 16:33:25
User entered 'Day 5'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:01

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:01

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	10 Sep 2020 16:33:25
User entered 'Day 6'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-16T06:43:53', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '06c22518-40af-4eba-9f7b-9076d65452ef'	System	16 Sep 2020 10:44:15
User entered 'None (1)'	System	16 Sep 2020 10:44:15

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-16T06:43:57', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '06c22518-40af-4eba-9f7b-9076d65452ef'	System	16 Sep 2020 10:44:15
User entered 'No (N)'	System	16 Sep 2020 10:44:15

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-16T06:44:01', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '06c22518-40af-4eba-9f7b-9076d65452ef'	System	16 Sep 2020 10:44:15
User entered 'No (N)'	System	16 Sep 2020 10:44:15

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-16T06:44:10', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '06c22518-40af-4eba-9f7b-9076d65452ef'	System	16 Sep 2020 10:44:15
User entered 'None (1)'	System	16 Sep 2020 10:44:15

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-16T06:44:13', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '06c22518-40af-4eba-9f7b-9076d65452ef'	System	16 Sep 2020 10:44:15
User entered '16 Sep 2020 06:44'	System	16 Sep 2020 10:44:15

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	10 Sep 2020 16:33:25
User entered 'Day 7'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:01

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:01

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	10 Sep 2020 16:33:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-10T12:59:54', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '73d41335-fc38-49e9-93bd-cc380c578930'	System	10 Sep 2020 17:00:49
User entered 'None (0)'	System	10 Sep 2020 17:00:49

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-10T13:00:02', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '73d41335-fc38-49e9-93bd-cc380c578930'	System	10 Sep 2020 17:00:49
User entered 'None (0)'	System	10 Sep 2020 17:00:49

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-10T13:00:08', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '73d41335-fc38-49e9-93bd-cc380c578930'	System	10 Sep 2020 17:00:49
User entered 'None (0)'	System	10 Sep 2020 17:00:49

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-10T13:00:12', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '73d41335-fc38-49e9-93bd-cc380c578930'	System	10 Sep 2020 17:00:49
User entered 'None (0)'	System	10 Sep 2020 17:00:49

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-10T13:00:14', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '73d41335-fc38-49e9-93bd-cc380c578930'	System	10 Sep 2020 17:00:49
User entered 'None (0)'	System	10 Sep 2020 17:00:49

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-10T13:00:17', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '73d41335-fc38-49e9-93bd-cc380c578930'	System	10 Sep 2020 17:00:49
User entered 'None (0)'	System	10 Sep 2020 17:00:49

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-10T13:00:32', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '73d41335-fc38-49e9-93bd-cc380c578930'	System	10 Sep 2020 17:00:49
User entered 'No (N)'	System	10 Sep 2020 17:00:49

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-10T13:00:40', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '73d41335-fc38-49e9-93bd-cc380c578930'	System	10 Sep 2020 17:00:49
User entered '10 Sep 2020 13:00'	System	10 Sep 2020 17:00:49

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '10 Sep 2020 12:32'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '10 Sep 2020 15:02'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	10 Sep 2020 16:33:25
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-11T06:46:09', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e98a6eb4-b25e-4631-bd54-033aabd75a36'	System	11 Sep 2020 10:46:47
User entered 'None (0)'	System	11 Sep 2020 10:46:47

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-11T06:46:14', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e98a6eb4-b25e-4631-bd54-033aabd75a36'	System	11 Sep 2020 10:46:47
User entered 'None (0)'	System	11 Sep 2020 10:46:47

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-11T06:46:17', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e98a6eb4-b25e-4631-bd54-033aabd75a36'	System	11 Sep 2020 10:46:47
User entered 'None (0)'	System	11 Sep 2020 10:46:47

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-11T06:46:21', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e98a6eb4-b25e-4631-bd54-033aabd75a36'	System	11 Sep 2020 10:46:47
User entered 'None (0)'	System	11 Sep 2020 10:46:47

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-11T06:46:24', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e98a6eb4-b25e-4631-bd54-033aabd75a36'	System	11 Sep 2020 10:46:47
User entered 'None (0)'	System	11 Sep 2020 10:46:47

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-11T06:46:27', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e98a6eb4-b25e-4631-bd54-033aabd75a36'	System	11 Sep 2020 10:46:47
User entered 'None (0)'	System	11 Sep 2020 10:46:47

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-11T06:46:38', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e98a6eb4-b25e-4631-bd54-033aabd75a36'	System	11 Sep 2020 10:46:47
User entered 'No (N)'	System	11 Sep 2020 10:46:47

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-11T06:46:46', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e98a6eb4-b25e-4631-bd54-033aabd75a36'	System	11 Sep 2020 10:46:47
User entered '11 Sep 2020 06:46'	System	11 Sep 2020 10:46:47

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '10 Sep 2020 15:57'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	10 Sep 2020 16:33:25
User entered 'Day 2'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-12T08:43:10', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'f36256d7-f89c-4868-989f-c9fd241a3e23'	System	12 Sep 2020 12:44:03
User entered 'None (0)'	System	12 Sep 2020 12:44:03

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-12T08:43:18', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'f36256d7-f89c-4868-989f-c9fd241a3e23'	System	12 Sep 2020 12:44:03
User entered 'None (0)'	System	12 Sep 2020 12:44:03

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-12T08:43:33', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'f36256d7-f89c-4868-989f-c9fd241a3e23'	System	12 Sep 2020 12:44:03
User entered 'None (0)'	System	12 Sep 2020 12:44:03

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-12T08:43:36', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'f36256d7-f89c-4868-989f-c9fd241a3e23'	System	12 Sep 2020 12:44:03
User entered 'None (0)'	System	12 Sep 2020 12:44:03

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-12T08:43:39', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'f36256d7-f89c-4868-989f-c9fd241a3e23'	System	12 Sep 2020 12:44:03
User entered 'None (0)'	System	12 Sep 2020 12:44:03

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-12T08:43:51', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'f36256d7-f89c-4868-989f-c9fd241a3e23'	System	12 Sep 2020 12:44:03
User entered 'None (0)'	System	12 Sep 2020 12:44:03

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-12T08:43:57', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'f36256d7-f89c-4868-989f-c9fd241a3e23'	System	12 Sep 2020 12:44:03
User entered 'No (N)'	System	12 Sep 2020 12:44:03

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-12T08:44:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'f36256d7-f89c-4868-989f-c9fd241a3e23'	System	12 Sep 2020 12:44:03
User entered '12 Sep 2020 08:44'	System	12 Sep 2020 12:44:03

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	10 Sep 2020 16:33:25
User entered 'Day 3'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-13T07:07:41', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'c83642ff-a239-4564-93a8-b3c70126f007'	System	13 Sep 2020 11:08:19
User entered 'None (0)'	System	13 Sep 2020 11:08:19

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-13T07:07:44', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'c83642ff-a239-4564-93a8-b3c70126f007'	System	13 Sep 2020 11:08:19
User entered 'None (0)'	System	13 Sep 2020 11:08:19

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-13T07:07:50', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'c83642ff-a239-4564-93a8-b3c70126f007'	System	13 Sep 2020 11:08:19
User entered 'None (0)'	System	13 Sep 2020 11:08:19

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-13T07:07:54', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'c83642ff-a239-4564-93a8-b3c70126f007'	System	13 Sep 2020 11:08:19
User entered 'None (0)'	System	13 Sep 2020 11:08:19

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-13T07:08:01', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'c83642ff-a239-4564-93a8-b3c70126f007'	System	13 Sep 2020 11:08:19
User entered 'None (0)'	System	13 Sep 2020 11:08:19

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-13T07:08:04', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'c83642ff-a239-4564-93a8-b3c70126f007'	System	13 Sep 2020 11:08:19
User entered 'None (0)'	System	13 Sep 2020 11:08:19

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-13T07:08:10', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'c83642ff-a239-4564-93a8-b3c70126f007'	System	13 Sep 2020 11:08:19
User entered 'No (N)'	System	13 Sep 2020 11:08:19

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-13T07:08:17', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'c83642ff-a239-4564-93a8-b3c70126f007'	System	13 Sep 2020 11:08:19
User entered '13 Sep 2020 07:08'	System	13 Sep 2020 11:08:19

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	10 Sep 2020 16:33:25
User entered 'Day 4'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-14T08:07:41', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'f6bc98af-8967-447b-ae28-c121c278864e'	System	14 Sep 2020 12:08:09
User entered 'None (0)'	System	14 Sep 2020 12:08:09

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-14T08:07:44', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'f6bc98af-8967-447b-ae28-c121c278864e'	System	14 Sep 2020 12:08:09
User entered 'None (0)'	System	14 Sep 2020 12:08:09

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-14T08:07:46', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'f6bc98af-8967-447b-ae28-c121c278864e'	System	14 Sep 2020 12:08:09
User entered 'None (0)'	System	14 Sep 2020 12:08:09

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-14T08:07:49', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'f6bc98af-8967-447b-ae28-c121c278864e'	System	14 Sep 2020 12:08:09
User entered 'None (0)'	System	14 Sep 2020 12:08:09

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-14T08:07:51', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'f6bc98af-8967-447b-ae28-c121c278864e'	System	14 Sep 2020 12:08:09
User entered 'None (0)'	System	14 Sep 2020 12:08:09

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-14T08:07:54', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'f6bc98af-8967-447b-ae28-c121c278864e'	System	14 Sep 2020 12:08:09
User entered 'None (0)'	System	14 Sep 2020 12:08:09

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-14T08:07:59', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'f6bc98af-8967-447b-ae28-c121c278864e'	System	14 Sep 2020 12:08:09
User entered 'No (N)'	System	14 Sep 2020 12:08:09

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-14T08:08:04', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'f6bc98af-8967-447b-ae28-c121c278864e'	System	14 Sep 2020 12:08:09
User entered '14 Sep 2020 08:08'	System	14 Sep 2020 12:08:09

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	10 Sep 2020 16:33:25
User entered 'Day 5'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:01

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) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	10 Sep 2020 16:33:25
User entered 'Day 6'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-16T06:44:25', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'f8f68e66-9f23-462a-99f8-23b508c9e858'	System	16 Sep 2020 10:45:06
User entered 'None (0)'	System	16 Sep 2020 10:45:06

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-16T06:44:28', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'f8f68e66-9f23-462a-99f8-23b508c9e858'	System	16 Sep 2020 10:45:06
User entered 'None (0)'	System	16 Sep 2020 10:45:06

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-16T06:44:33', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'f8f68e66-9f23-462a-99f8-23b508c9e858'	System	16 Sep 2020 10:45:06
User entered 'None (0)'	System	16 Sep 2020 10:45:06

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-16T06:44:37', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'f8f68e66-9f23-462a-99f8-23b508c9e858'	System	16 Sep 2020 10:45:06
User entered 'None (0)'	System	16 Sep 2020 10:45:06

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-16T06:44:40', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'f8f68e66-9f23-462a-99f8-23b508c9e858'	System	16 Sep 2020 10:45:06
User entered 'None (0)'	System	16 Sep 2020 10:45:06

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-16T06:44:43', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'f8f68e66-9f23-462a-99f8-23b508c9e858'	System	16 Sep 2020 10:45:06
User entered 'None (0)'	System	16 Sep 2020 10:45:06

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-16T06:44:58', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'f8f68e66-9f23-462a-99f8-23b508c9e858'	System	16 Sep 2020 10:45:06
User entered 'No (N)'	System	16 Sep 2020 10:45:06

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-09-16T06:45:02', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'f8f68e66-9f23-462a-99f8-23b508c9e858'	System	16 Sep 2020 10:45:06
User entered '16 Sep 2020 06:45'	System	16 Sep 2020 10:45:06

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	10 Sep 2020 16:33:25
User entered 'Day 7'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:01

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) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:17:18

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 16:33:25

US3902060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 16:33:25

US3902060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	18 Sep 2020 19:18:53

US3902060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '18 Sep 2020'	Bram Swarr (b) (4)	18 Sep 2020 19:18:53

US3902060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Contact Made (CONTACT MADE)'	Bram Swarr (b) (4)	18 Sep 2020 19:18:53

US3902060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	18 Sep 2020 19:18:53

US3902060

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	18 Sep 2020 19:19:00

US3902060

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'I'	System	18 Sep 2020 19:19:00

US3902060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:48:42

US3902060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 21:48:42

US3902060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Sep 2020 21:48:42

US3902060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:48:42

US3902060

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:48:49

US3902060

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'I'	System	24 Sep 2020 21:48:49

US3902060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 22:47:39

US3902060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	07 Oct 2020 13:18:47
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'data is correct. PD created' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 22:48:23
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	05 Oct 2020 22:47:39
User entered '5 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 22:47:39

US3902060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 22:47:39

US3902060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 22:47:39

US3902060

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 22:47:49

US3902060

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'I'	System	05 Oct 2020 22:47:49

US3902060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 13:52:53

US3902060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '14 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 13:52:53

US3902060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Oct 2020 13:52:53

US3902060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'VISIT2'	System	16 Oct 2020 13:52:53

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '14 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '09:19'	(b) (4), (b) (6)	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered '14 Oct 2020 09:19'	System	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '97.4' F	(b) (4), (b) (6)	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '78'	(b) (4), (b) (6)	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'bpm'	System	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '16'	(b) (4), (b) (6)	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'breaths/min'	System	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '128'	(b) (4), (b) (6)	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'mmHg'	System	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '88'	(b) (4), (b) (6)	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'mmHg'	System	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '14 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '11:55'	(b) (4), (b) (6)	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered '14 Oct 2020 11:55'	System	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '97.7' F	(b) (4), (b) (6)	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '64'	(b) (4), (b) (6)	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'bpm'	System	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '16'	(b) (4), (b) (6)	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'breaths/min'	System	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '130'	(b) (4), (b) (6)	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'mmHg'	System	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '70'	(b) (4), (b) (6)	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'mmHg'	System	16 Oct 2020 13:55:35

US3902060

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 13:55:53

US3902060

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 13:55:53

US3902060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	14 Oct 2020 15:38:50

US3902060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:01

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Taylor Atkinson (b) (4)	14 Oct 2020 15:38:50

US3902060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:01

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)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Taylor Atkinson (b) (4)	14 Oct 2020 15:38:50

US3902060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'MRNA-1273 OR PLACEBO'	System	14 Oct 2020 15:38:50

US3902060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '14 Oct 2020'	Taylor Atkinson (b) (4)	14 Oct 2020 15:38:50

US3902060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '11:20'	Taylor Atkinson (b) (4)	14 Oct 2020 15:38:50

US3902060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:01

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered '14 Oct 2020 11:20'	System	14 Oct 2020 15:38:50

US3902060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:01

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Left Arm (LEFT ARM)'	Taylor Atkinson (b) (4)	14 Oct 2020 15:38:50

US3902060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:01

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'ONCE'	System	14 Oct 2020 15:38:50

US3902060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'INTRAMUSCULAR'	System	14 Oct 2020 15:38:50

US3902060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 13:57:31

US3902060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '14 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 13:57:31

US3902060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:01

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '10:40'	(b) (4), (b) (6)	16 Oct 2020 13:57:31

US3902060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered '14 Oct 2020 10:40'	System	16 Oct 2020 13:57:31

US3902060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:19:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '14 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 13:58:36

US3902060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:19:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	16 Oct 2020 13:58:36

US3902060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:19:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 13:58:36

US3902060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:19:01

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '10:42'	(b) (4), (b) (6)	16 Oct 2020 13:58:36

US3902060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered '14 Oct 2020 10:42'	System	16 Oct 2020 13:58:36

US3902060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:19:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	16 Oct 2020 13:58:36

US3902060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:19:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 13:58:36

US3902060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:19:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '10:42'	(b) (4), (b) (6)	16 Oct 2020 13:58:36

US3902060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered '14 Oct 2020 10:42'	System	16 Oct 2020 13:58:36

US3902060

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 14:00:46

US3902060

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered '1'	System	16 Oct 2020 14:00:46

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	14 Oct 2020 15:38:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T11:52:58', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '373b780b-623e-4fed-b34b-5d90f135a3b2'	System	14 Oct 2020 15:53:24
User entered 'Yes (Y)'	System	14 Oct 2020 15:53:24

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T11:53:04', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '373b780b-623e-4fed-b34b-5d90f135a3b2'	System	14 Oct 2020 15:53:24
User entered '97.7'	System	14 Oct 2020 15:53:24

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T11:53:10', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '373b780b-623e-4fed-b34b-5d90f135a3b2'	System	14 Oct 2020 15:53:24
User entered 'No (N)'	System	14 Oct 2020 15:53:24

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T11:53:19', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '373b780b-623e-4fed-b34b-5d90f135a3b2'	System	14 Oct 2020 15:53:24
User entered '14 Oct 2020 11:53'	System	14 Oct 2020 15:53:24

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '14 Oct 2020 11:40'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '14 Oct 2020 14:10'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	14 Oct 2020 15:38:50
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T20:43:50', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'afdd3852-4da5-45d0-91de-8840aed9dc42'	System	15 Oct 2020 00:44:16
User entered 'Yes (Y)'	System	15 Oct 2020 00:44:16

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T20:43:55', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'afdd3852-4da5-45d0-91de-8840aed9dc42'	System	15 Oct 2020 00:44:16
User entered '97.7'	System	15 Oct 2020 00:44:16

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T20:44:01', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'afdd3852-4da5-45d0-91de-8840aed9dc42'	System	15 Oct 2020 00:44:16
User entered 'No (N)'	System	15 Oct 2020 00:44:16

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T20:44:15', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'afdd3852-4da5-45d0-91de-8840aed9dc42'	System	15 Oct 2020 00:44:16
User entered '14 Oct 2020 20:44'	System	15 Oct 2020 00:44:16

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '14 Oct 2020 15:05'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	14 Oct 2020 15:38:50
User entered 'Day 2'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-15T20:01:43', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '93bf65f4-f1e2-4f0f-a713-ff0a49f4a510'	System	16 Oct 2020 00:02:44
User entered 'Yes (Y)'	System	16 Oct 2020 00:02:44

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-15T20:01:50', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '93bf65f4-f1e2-4f0f-a713-ff0a49f4a510'	System	16 Oct 2020 00:02:44
User entered '97.9'	System	16 Oct 2020 00:02:44

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-15T20:01:59', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '93bf65f4-f1e2-4f0f-a713-ff0a49f4a510'	System	16 Oct 2020 00:02:44
User entered 'Yes (Y)'	System	16 Oct 2020 00:02:44

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Entered' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 15:00:42
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-15T20:02:34', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '93bf65f4-f1e2-4f0f-a713-ff0a49f4a510'	Taylor Atkinson (b) (4)	21 Oct 2020 23:01:32
User entered '1'	System	16 Oct 2020 00:02:44

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-15T20:02:34', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '93bf65f4-f1e2-4f0f-a713-ff0a49f4a510'	System	16 Oct 2020 00:02:44
User entered '0'	System	16 Oct 2020 00:02:44

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-15T20:02:41', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '93bf65f4-f1e2-4f0f-a713-ff0a49f4a510'	System	16 Oct 2020 00:02:44
User entered '15 Oct 2020 20:02'	System	16 Oct 2020 00:02:44

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	14 Oct 2020 15:38:50
User entered 'Day 3'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-16T20:59:13', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '0a037bd5-1f0e-42a6-a20f-db7700d73fb6'	System	17 Oct 2020 00:59:40
User entered 'Yes (Y)'	System	17 Oct 2020 00:59:40

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-16T20:59:25', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '0a037bd5-1f0e-42a6-a20f-db7700d73fb6'	System	17 Oct 2020 00:59:40
User entered '97.7'	System	17 Oct 2020 00:59:40

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-16T20:59:32', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '0a037bd5-1f0e-42a6-a20f-db7700d73fb6'	System	17 Oct 2020 00:59:40
User entered 'No (N)'	System	17 Oct 2020 00:59:40

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-16T20:59:37', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '0a037bd5-1f0e-42a6-a20f-db7700d73fb6'	System	17 Oct 2020 00:59:40
User entered '16 Oct 2020 20:59'	System	17 Oct 2020 00:59:40

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	14 Oct 2020 15:38:50
User entered 'Day 4'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-17T22:19:27', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e81ededf-9a47-4a7c-97a3-f937dcfa2b8f'	System	18 Oct 2020 02:19:51
User entered 'Yes (Y)'	System	18 Oct 2020 02:19:51

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-17T22:19:38', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e81ededf-9a47-4a7c-97a3-f937dcfa2b8f'	System	18 Oct 2020 02:19:51
User entered '97.7'	System	18 Oct 2020 02:19:51

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-17T22:19:43', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e81ededf-9a47-4a7c-97a3-f937dcfa2b8f'	System	18 Oct 2020 02:19:51
User entered 'No (N)'	System	18 Oct 2020 02:19:51

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-17T22:19:47', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e81ededf-9a47-4a7c-97a3-f937dcfa2b8f'	System	18 Oct 2020 02:19:51
User entered '17 Oct 2020 22:19'	System	18 Oct 2020 02:19:51

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	14 Oct 2020 15:38:50
User entered 'Day 5'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-18T20:41:54', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '62592895-e758-4137-8bdb-8a18fe3e418d'	System	19 Oct 2020 00:42:30
User entered 'Yes (Y)'	System	19 Oct 2020 00:42:30

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-18T20:42:08', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '62592895-e758-4137-8bdb-8a18fe3e418d'	System	19 Oct 2020 00:42:30
User entered '97.8'	System	19 Oct 2020 00:42:30

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-18T20:42:18', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '62592895-e758-4137-8bdb-8a18fe3e418d'	System	19 Oct 2020 00:42:30
User entered 'No (N)'	System	19 Oct 2020 00:42:30

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-18T20:42:26', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '62592895-e758-4137-8bdb-8a18fe3e418d'	System	19 Oct 2020 00:42:30
User entered '18 Oct 2020 20:42'	System	19 Oct 2020 00:42:30

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	14 Oct 2020 15:38:50
User entered 'Day 6'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-20T02:38:50', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '37a9f03a-ec07-4cec-ad74-427c211122b0'	System	20 Oct 2020 06:39:10
User entered 'Yes (Y)'	System	20 Oct 2020 06:39:10

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-20T02:38:57', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '37a9f03a-ec07-4cec-ad74-427c211122b0'	System	20 Oct 2020 06:39:10
User entered '97.7'	System	20 Oct 2020 06:39:10

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-20T02:39:01', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '37a9f03a-ec07-4cec-ad74-427c211122b0'	System	20 Oct 2020 06:39:10
User entered 'No (N)'	System	20 Oct 2020 06:39:10

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-20T02:39:06', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '37a9f03a-ec07-4cec-ad74-427c211122b0'	System	20 Oct 2020 06:39:10
User entered '20 Oct 2020 02:39'	System	20 Oct 2020 06:39:10

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	14 Oct 2020 15:38:50
User entered 'Day 7'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-21T03:18:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '2ae6d2bc-f126-43d1-91da-84f32486bf0f'	System	21 Oct 2020 07:18:16
User entered 'Yes (Y)'	System	21 Oct 2020 07:18:16

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-21T03:18:07', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '2ae6d2bc-f126-43d1-91da-84f32486bf0f'	System	21 Oct 2020 07:18:16
User entered '97.7'	System	21 Oct 2020 07:18:16

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-21T03:18:11', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '2ae6d2bc-f126-43d1-91da-84f32486bf0f'	System	21 Oct 2020 07:18:16
User entered 'No (N)'	System	21 Oct 2020 07:18:16

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-21T03:18:14', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '2ae6d2bc-f126-43d1-91da-84f32486bf0f'	System	21 Oct 2020 07:18:16
User entered '21 Oct 2020 03:18'	System	21 Oct 2020 07:18:16

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	14 Oct 2020 15:38:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T11:54:16', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '1d0c5393-68c2-4681-bc26-a7f06a5e4395'	System	14 Oct 2020 15:54:41
User entered 'None (1)'	System	14 Oct 2020 15:54:41

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T11:54:21', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '1d0c5393-68c2-4681-bc26-a7f06a5e4395'	System	14 Oct 2020 15:54:41
User entered 'No (N)'	System	14 Oct 2020 15:54:41

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T11:54:26', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '1d0c5393-68c2-4681-bc26-a7f06a5e4395'	System	14 Oct 2020 15:54:41
User entered 'No (N)'	System	14 Oct 2020 15:54:41

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T11:54:35', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '1d0c5393-68c2-4681-bc26-a7f06a5e4395'	System	14 Oct 2020 15:54:41
User entered 'None (1)'	System	14 Oct 2020 15:54:41

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T11:54:38', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '1d0c5393-68c2-4681-bc26-a7f06a5e4395'	System	14 Oct 2020 15:54:41
User entered '14 Oct 2020 11:54'	System	14 Oct 2020 15:54:41

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '14 Oct 2020 11:40'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '14 Oct 2020 14:10'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	14 Oct 2020 15:38:50
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T20:44:42', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '3e8dfdfc-7c7a-4e2e-9fb5-8a04ae1e12a8'	System	15 Oct 2020 00:45:05
User entered 'Does not interfere with activity (2)'	System	15 Oct 2020 00:45:05

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T20:44:45', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '3e8dfdfc-7c7a-4e2e-9fb5-8a04ae1e12a8'	System	15 Oct 2020 00:45:05
User entered 'No (N)'	System	15 Oct 2020 00:45:05

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T20:44:50', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '3e8dfdfc-7c7a-4e2e-9fb5-8a04ae1e12a8'	System	15 Oct 2020 00:45:05
User entered 'No (N)'	System	15 Oct 2020 00:45:05

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T20:44:59', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '3e8dfdfc-7c7a-4e2e-9fb5-8a04ae1e12a8'	System	15 Oct 2020 00:45:05
User entered 'None (1)'	System	15 Oct 2020 00:45:05

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T20:45:03', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '3e8dfdfc-7c7a-4e2e-9fb5-8a04ae1e12a8'	System	15 Oct 2020 00:45:05
User entered '14 Oct 2020 20:45'	System	15 Oct 2020 00:45:05

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '14 Oct 2020 15:05'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	14 Oct 2020 15:38:50
User entered 'Day 2'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-15T20:02:56', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '92a3aa90-4fbc-4f3a-9511-b98f1d4be9cb'	System	16 Oct 2020 00:03:20
User entered 'Does not interfere with activity (2)'	System	16 Oct 2020 00:03:20

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-15T20:02:59', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '92a3aa90-4fbc-4f3a-9511-b98f1d4be9cb'	System	16 Oct 2020 00:03:20
User entered 'No (N)'	System	16 Oct 2020 00:03:20

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-15T20:03:04', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '92a3aa90-4fbc-4f3a-9511-b98f1d4be9cb'	System	16 Oct 2020 00:03:20
User entered 'No (N)'	System	16 Oct 2020 00:03:20

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-15T20:03:12', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '92a3aa90-4fbc-4f3a-9511-b98f1d4be9cb'	System	16 Oct 2020 00:03:20
User entered 'None (1)'	System	16 Oct 2020 00:03:20

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-15T20:03:18', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '92a3aa90-4fbc-4f3a-9511-b98f1d4be9cb'	System	16 Oct 2020 00:03:20
User entered '15 Oct 2020 20:03'	System	16 Oct 2020 00:03:20

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	14 Oct 2020 15:38:50
User entered 'Day 3'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-16T20:59:44', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '3e7f5cbc-c8ca-4e42-afa3-40d9cb85e690'	System	17 Oct 2020 01:00:42
User entered 'None (1)'	System	17 Oct 2020 01:00:42

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-16T20:59:49', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '3e7f5cbc-c8ca-4e42-afa3-40d9cb85e690'	System	17 Oct 2020 01:00:42
User entered 'No (N)'	System	17 Oct 2020 01:00:42

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-16T20:59:53', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '3e7f5cbc-c8ca-4e42-afa3-40d9cb85e690'	System	17 Oct 2020 01:00:42
User entered 'No (N)'	System	17 Oct 2020 01:00:42

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-16T21:00:33', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '3e7f5cbc-c8ca-4e42-afa3-40d9cb85e690'	System	17 Oct 2020 01:00:42
User entered 'Does not interfere with activity (2)'	System	17 Oct 2020 01:00:42

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-16T21:00:38', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '3e7f5cbc-c8ca-4e42-afa3-40d9cb85e690'	System	17 Oct 2020 01:00:42
User entered '16 Oct 2020 21:00'	System	17 Oct 2020 01:00:42

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	14 Oct 2020 15:38:50
User entered 'Day 4'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-17T22:19:53', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '064d8380-bd72-46fd-988f-2a9e4e4c590e'	System	18 Oct 2020 02:20:14
User entered 'None (1)'	System	18 Oct 2020 02:20:14

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-17T22:19:59', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '064d8380-bd72-46fd-988f-2a9e4e4c590e'	System	18 Oct 2020 02:20:14
User entered 'No (N)'	System	18 Oct 2020 02:20:14

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-17T22:20:02', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '064d8380-bd72-46fd-988f-2a9e4e4c590e'	System	18 Oct 2020 02:20:14
User entered 'No (N)'	System	18 Oct 2020 02:20:14

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-17T22:20:06', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '064d8380-bd72-46fd-988f-2a9e4e4c590e'	System	18 Oct 2020 02:20:14
User entered 'None (1)'	System	18 Oct 2020 02:20:14

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-17T22:20:10', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '064d8380-bd72-46fd-988f-2a9e4e4c590e'	System	18 Oct 2020 02:20:14
User entered '17 Oct 2020 22:20'	System	18 Oct 2020 02:20:14

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	14 Oct 2020 15:38:50
User entered 'Day 5'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-18T20:42:31', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'ca1b84cc-429c-4437-9532-e330725118bb'	System	19 Oct 2020 00:43:36
User entered 'None (1)'	System	19 Oct 2020 00:43:36

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-18T20:42:34', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'ca1b84cc-429c-4437-9532-e330725118bb'	System	19 Oct 2020 00:43:36
User entered 'No (N)'	System	19 Oct 2020 00:43:36

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-18T20:42:38', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'ca1b84cc-429c-4437-9532-e330725118bb'	System	19 Oct 2020 00:43:36
User entered 'No (N)'	System	19 Oct 2020 00:43:36

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-18T20:42:46', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'ca1b84cc-429c-4437-9532-e330725118bb'	System	19 Oct 2020 00:43:36
User entered 'None (1)'	System	19 Oct 2020 00:43:36

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-18T20:43:31', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'ca1b84cc-429c-4437-9532-e330725118bb'	System	19 Oct 2020 00:43:36
User entered '18 Oct 2020 20:43'	System	19 Oct 2020 00:43:36

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	14 Oct 2020 15:38:50
User entered 'Day 6'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-20T02:39:12', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '60af790c-d828-4233-9585-f80f3bedcea6'	System	20 Oct 2020 06:39:26
User entered 'None (1)'	System	20 Oct 2020 06:39:26

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-20T02:39:15', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '60af790c-d828-4233-9585-f80f3bedcea6'	System	20 Oct 2020 06:39:26
User entered 'No (N)'	System	20 Oct 2020 06:39:26

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-20T02:39:18', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '60af790c-d828-4233-9585-f80f3bedcea6'	System	20 Oct 2020 06:39:26
User entered 'No (N)'	System	20 Oct 2020 06:39:26

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-20T02:39:21', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '60af790c-d828-4233-9585-f80f3bedcea6'	System	20 Oct 2020 06:39:26
User entered 'None (1)'	System	20 Oct 2020 06:39:26

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-20T02:39:24', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '60af790c-d828-4233-9585-f80f3bedcea6'	System	20 Oct 2020 06:39:26
User entered '20 Oct 2020 02:39'	System	20 Oct 2020 06:39:26

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	14 Oct 2020 15:38:50
User entered 'Day 7'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-21T03:18:28', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '0d0e0d77-c00f-4cd3-980f-8e58ee6c65b1'	System	21 Oct 2020 07:18:45
User entered 'None (1)'	System	21 Oct 2020 07:18:45

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-21T03:18:32', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '0d0e0d77-c00f-4cd3-980f-8e58ee6c65b1'	System	21 Oct 2020 07:18:45
User entered 'No (N)'	System	21 Oct 2020 07:18:45

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-21T03:18:37', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '0d0e0d77-c00f-4cd3-980f-8e58ee6c65b1'	System	21 Oct 2020 07:18:45
User entered 'No (N)'	System	21 Oct 2020 07:18:45

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-21T03:18:40', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '0d0e0d77-c00f-4cd3-980f-8e58ee6c65b1'	System	21 Oct 2020 07:18:45
User entered 'None (1)'	System	21 Oct 2020 07:18:45

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-21T03:18:43', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '0d0e0d77-c00f-4cd3-980f-8e58ee6c65b1'	System	21 Oct 2020 07:18:45
User entered '21 Oct 2020 03:18'	System	21 Oct 2020 07:18:45

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	14 Oct 2020 15:38:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T11:54:44', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'c7a41cb5-51f6-4fae-ab2b-6800492b5d71'	System	14 Oct 2020 15:55:09
User entered 'None (0)'	System	14 Oct 2020 15:55:09

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T11:54:46', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'c7a41cb5-51f6-4fae-ab2b-6800492b5d71'	System	14 Oct 2020 15:55:09
User entered 'None (0)'	System	14 Oct 2020 15:55:09

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T11:54:49', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'c7a41cb5-51f6-4fae-ab2b-6800492b5d71'	System	14 Oct 2020 15:55:09
User entered 'None (0)'	System	14 Oct 2020 15:55:09

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T11:54:55', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'c7a41cb5-51f6-4fae-ab2b-6800492b5d71'	System	14 Oct 2020 15:55:09
User entered 'None (0)'	System	14 Oct 2020 15:55:09

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T11:54:58', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'c7a41cb5-51f6-4fae-ab2b-6800492b5d71'	System	14 Oct 2020 15:55:09
User entered 'None (0)'	System	14 Oct 2020 15:55:09

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T11:55:01', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'c7a41cb5-51f6-4fae-ab2b-6800492b5d71'	System	14 Oct 2020 15:55:09
User entered 'None (0)'	System	14 Oct 2020 15:55:09

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T11:55:05', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'c7a41cb5-51f6-4fae-ab2b-6800492b5d71'	System	14 Oct 2020 15:55:09
User entered 'No (N)'	System	14 Oct 2020 15:55:09

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T11:55:08', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'c7a41cb5-51f6-4fae-ab2b-6800492b5d71'	System	14 Oct 2020 15:55:09
User entered '14 Oct 2020 11:55'	System	14 Oct 2020 15:55:09

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '14 Oct 2020 11:40'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '14 Oct 2020 14:10'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	14 Oct 2020 15:38:50
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T20:45:10', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '6f051a1e-1599-40cd-a585-d7e8f0f691b6'	System	15 Oct 2020 00:45:39
User entered 'None (0)'	System	15 Oct 2020 00:45:39

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T20:45:13', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '6f051a1e-1599-40cd-a585-d7e8f0f691b6'	System	15 Oct 2020 00:45:39
User entered 'None (0)'	System	15 Oct 2020 00:45:39

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T20:45:16', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '6f051a1e-1599-40cd-a585-d7e8f0f691b6'	System	15 Oct 2020 00:45:39
User entered 'None (0)'	System	15 Oct 2020 00:45:39

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T20:45:20', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '6f051a1e-1599-40cd-a585-d7e8f0f691b6'	System	15 Oct 2020 00:45:39
User entered 'None (0)'	System	15 Oct 2020 00:45:39

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T20:45:23', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '6f051a1e-1599-40cd-a585-d7e8f0f691b6'	System	15 Oct 2020 00:45:39
User entered 'None (0)'	System	15 Oct 2020 00:45:39

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T20:45:27', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '6f051a1e-1599-40cd-a585-d7e8f0f691b6'	System	15 Oct 2020 00:45:39
User entered 'None (0)'	System	15 Oct 2020 00:45:39

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T20:45:34', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '6f051a1e-1599-40cd-a585-d7e8f0f691b6'	System	15 Oct 2020 00:45:39
User entered 'No (N)'	System	15 Oct 2020 00:45:39

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-14T20:45:37', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '6f051a1e-1599-40cd-a585-d7e8f0f691b6'	System	15 Oct 2020 00:45:39
User entered '14 Oct 2020 20:45'	System	15 Oct 2020 00:45:39

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '14 Oct 2020 15:05'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	14 Oct 2020 15:38:50
User entered 'Day 2'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-15T20:03:29', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '0332cc33-54c9-4608-99b0-6f1ffc95c15b'	System	16 Oct 2020 00:04:09
User entered 'None (0)'	System	16 Oct 2020 00:04:09

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-15T20:03:39', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '0332cc33-54c9-4608-99b0-6f1ffc95c15b'	System	16 Oct 2020 00:04:09
User entered 'No interference with activity (1)'	System	16 Oct 2020 00:04:09

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-15T20:03:44', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '0332cc33-54c9-4608-99b0-6f1ffc95c15b'	System	16 Oct 2020 00:04:09
User entered 'No interference with activity (1)'	System	16 Oct 2020 00:04:09

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-15T20:03:48', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '0332cc33-54c9-4608-99b0-6f1ffc95c15b'	System	16 Oct 2020 00:04:09
User entered 'None (0)'	System	16 Oct 2020 00:04:09

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-15T20:03:51', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '0332cc33-54c9-4608-99b0-6f1ffc95c15b'	System	16 Oct 2020 00:04:09
User entered 'None (0)'	System	16 Oct 2020 00:04:09

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-15T20:03:54', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '0332cc33-54c9-4608-99b0-6f1ffc95c15b'	System	16 Oct 2020 00:04:09
User entered 'None (0)'	System	16 Oct 2020 00:04:09

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-15T20:03:58', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '0332cc33-54c9-4608-99b0-6f1ffc95c15b'	System	16 Oct 2020 00:04:09
User entered 'No (N)'	System	16 Oct 2020 00:04:09

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-15T20:04:03', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '0332cc33-54c9-4608-99b0-6f1ffc95c15b'	System	16 Oct 2020 00:04:09
User entered '15 Oct 2020 20:04'	System	16 Oct 2020 00:04:09

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	14 Oct 2020 15:38:50
User entered 'Day 3'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-16T21:00:43', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e2140a3a-5df1-4abf-a244-f7cacb691fe9'	System	17 Oct 2020 01:01:23
User entered 'None (0)'	System	17 Oct 2020 01:01:23

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-16T21:00:45', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e2140a3a-5df1-4abf-a244-f7cacb691fe9'	System	17 Oct 2020 01:01:23
User entered 'None (0)'	System	17 Oct 2020 01:01:23

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-16T21:00:48', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e2140a3a-5df1-4abf-a244-f7cacb691fe9'	System	17 Oct 2020 01:01:23
User entered 'None (0)'	System	17 Oct 2020 01:01:23

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-16T21:00:51', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e2140a3a-5df1-4abf-a244-f7cacb691fe9'	System	17 Oct 2020 01:01:23
User entered 'None (0)'	System	17 Oct 2020 01:01:23

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-16T21:00:54', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e2140a3a-5df1-4abf-a244-f7cacb691fe9'	System	17 Oct 2020 01:01:23
User entered 'None (0)'	System	17 Oct 2020 01:01:23

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-16T21:00:57', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e2140a3a-5df1-4abf-a244-f7cacb691fe9'	System	17 Oct 2020 01:01:23
User entered 'None (0)'	System	17 Oct 2020 01:01:23

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-16T21:01:17', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e2140a3a-5df1-4abf-a244-f7cacb691fe9'	System	17 Oct 2020 01:01:23
User entered 'No (N)'	System	17 Oct 2020 01:01:23

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-16T21:01:20', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e2140a3a-5df1-4abf-a244-f7cacb691fe9'	System	17 Oct 2020 01:01:23
User entered '16 Oct 2020 21:01'	System	17 Oct 2020 01:01:23

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	14 Oct 2020 15:38:50
User entered 'Day 4'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-17T22:20:31', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e5b0377f-1217-41cc-a793-0af963692990'	System	18 Oct 2020 02:21:09
User entered 'None (0)'	System	18 Oct 2020 02:21:09

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-17T22:20:42', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e5b0377f-1217-41cc-a793-0af963692990'	System	18 Oct 2020 02:21:09
User entered 'None (0)'	System	18 Oct 2020 02:21:09

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-17T22:20:48', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e5b0377f-1217-41cc-a793-0af963692990'	System	18 Oct 2020 02:21:09
User entered 'None (0)'	System	18 Oct 2020 02:21:09

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-17T22:20:51', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e5b0377f-1217-41cc-a793-0af963692990'	System	18 Oct 2020 02:21:09
User entered 'None (0)'	System	18 Oct 2020 02:21:09

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-17T22:20:54', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e5b0377f-1217-41cc-a793-0af963692990'	System	18 Oct 2020 02:21:09
User entered 'None (0)'	System	18 Oct 2020 02:21:09

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-17T22:20:56', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e5b0377f-1217-41cc-a793-0af963692990'	System	18 Oct 2020 02:21:09
User entered 'None (0)'	System	18 Oct 2020 02:21:09

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-17T22:21:01', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e5b0377f-1217-41cc-a793-0af963692990'	System	18 Oct 2020 02:21:09
User entered 'No (N)'	System	18 Oct 2020 02:21:09

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-17T22:21:04', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e5b0377f-1217-41cc-a793-0af963692990'	System	18 Oct 2020 02:21:09
User entered '17 Oct 2020 22:21'	System	18 Oct 2020 02:21:09

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	14 Oct 2020 15:38:50
User entered 'Day 5'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-18T20:43:36', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '0f4c0539-c7ed-4c89-a1f5-c05edb6a8a3d'	System	19 Oct 2020 00:44:08
User entered 'None (0)'	System	19 Oct 2020 00:44:08

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-18T20:43:39', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '0f4c0539-c7ed-4c89-a1f5-c05edb6a8a3d'	System	19 Oct 2020 00:44:08
User entered 'None (0)'	System	19 Oct 2020 00:44:08

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-18T20:43:42', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '0f4c0539-c7ed-4c89-a1f5-c05edb6a8a3d'	System	19 Oct 2020 00:44:08
User entered 'None (0)'	System	19 Oct 2020 00:44:08

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-18T20:43:45', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '0f4c0539-c7ed-4c89-a1f5-c05edb6a8a3d'	System	19 Oct 2020 00:44:08
User entered 'None (0)'	System	19 Oct 2020 00:44:08

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-18T20:43:47', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '0f4c0539-c7ed-4c89-a1f5-c05edb6a8a3d'	System	19 Oct 2020 00:44:08
User entered 'None (0)'	System	19 Oct 2020 00:44:08

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-18T20:43:49', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '0f4c0539-c7ed-4c89-a1f5-c05edb6a8a3d'	System	19 Oct 2020 00:44:08
User entered 'None (0)'	System	19 Oct 2020 00:44:08

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-18T20:43:58', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '0f4c0539-c7ed-4c89-a1f5-c05edb6a8a3d'	System	19 Oct 2020 00:44:08
User entered 'No (N)'	System	19 Oct 2020 00:44:08

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-18T20:44:02', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '0f4c0539-c7ed-4c89-a1f5-c05edb6a8a3d'	System	19 Oct 2020 00:44:08
User entered '18 Oct 2020 20:44'	System	19 Oct 2020 00:44:08

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	14 Oct 2020 15:38:50
User entered 'Day 6'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-20T02:39:28', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e1b5c4b5-aa83-455a-b65b-9e6d00ac5491'	System	20 Oct 2020 06:39:50
User entered 'None (0)'	System	20 Oct 2020 06:39:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-20T02:39:30', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e1b5c4b5-aa83-455a-b65b-9e6d00ac5491'	System	20 Oct 2020 06:39:50
User entered 'None (0)'	System	20 Oct 2020 06:39:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-20T02:39:32', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e1b5c4b5-aa83-455a-b65b-9e6d00ac5491'	System	20 Oct 2020 06:39:50
User entered 'None (0)'	System	20 Oct 2020 06:39:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-20T02:39:35', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e1b5c4b5-aa83-455a-b65b-9e6d00ac5491'	System	20 Oct 2020 06:39:50
User entered 'None (0)'	System	20 Oct 2020 06:39:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-20T02:39:37', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e1b5c4b5-aa83-455a-b65b-9e6d00ac5491'	System	20 Oct 2020 06:39:50
User entered 'None (0)'	System	20 Oct 2020 06:39:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-20T02:39:39', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e1b5c4b5-aa83-455a-b65b-9e6d00ac5491'	System	20 Oct 2020 06:39:50
User entered 'None (0)'	System	20 Oct 2020 06:39:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-20T02:39:43', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e1b5c4b5-aa83-455a-b65b-9e6d00ac5491'	System	20 Oct 2020 06:39:50
User entered 'No (N)'	System	20 Oct 2020 06:39:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-20T02:39:48', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e1b5c4b5-aa83-455a-b65b-9e6d00ac5491'	System	20 Oct 2020 06:39:50
User entered '20 Oct 2020 02:39'	System	20 Oct 2020 06:39:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
Data entry locked.	System	14 Oct 2020 15:38:50
User entered 'Day 7'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-21T03:18:47', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '3bf46e7b-a98a-4424-8469-a6e900b8a33a'	System	21 Oct 2020 07:19:12
User entered 'None (0)'	System	21 Oct 2020 07:19:12

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-21T03:18:49', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '3bf46e7b-a98a-4424-8469-a6e900b8a33a'	System	21 Oct 2020 07:19:12
User entered 'None (0)'	System	21 Oct 2020 07:19:12

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-21T03:18:52', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '3bf46e7b-a98a-4424-8469-a6e900b8a33a'	System	21 Oct 2020 07:19:12
User entered 'None (0)'	System	21 Oct 2020 07:19:12

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-21T03:18:54', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '3bf46e7b-a98a-4424-8469-a6e900b8a33a'	System	21 Oct 2020 07:19:12
User entered 'None (0)'	System	21 Oct 2020 07:19:12

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-21T03:18:55', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '3bf46e7b-a98a-4424-8469-a6e900b8a33a'	System	21 Oct 2020 07:19:12
User entered 'None (0)'	System	21 Oct 2020 07:19:12

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-21T03:18:59', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '3bf46e7b-a98a-4424-8469-a6e900b8a33a'	System	21 Oct 2020 07:19:12
User entered 'None (0)'	System	21 Oct 2020 07:19:12

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-21T03:19:04', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '3bf46e7b-a98a-4424-8469-a6e900b8a33a'	System	21 Oct 2020 07:19:12
User entered 'No (N)'	System	21 Oct 2020 07:19:12

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-10-21T03:19:07', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '3bf46e7b-a98a-4424-8469-a6e900b8a33a'	System	21 Oct 2020 07:19:12
User entered '21 Oct 2020 03:19'	System	21 Oct 2020 07:19:12

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 15:38:50

US3902060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:17:18
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 15:38:50

US3902060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	21 Oct 2020 22:51:29

US3902060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '21 Oct 2020'	Taylor Atkinson (b) (4)	21 Oct 2020 22:51:29

US3902060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Contact Made (CONTACT MADE)'	Taylor Atkinson (b) (4)	21 Oct 2020 22:51:29

US3902060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Taylor Atkinson (b) (4)	21 Oct 2020 22:51:29

US3902060

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	21 Oct 2020 23:01:41

US3902060

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'I'	System	21 Oct 2020 23:01:41

US3902060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	11 Nov 2020 21:31:47

US3902060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '29 Oct 2020'	Bram Swarr (b) (4)	11 Nov 2020 21:31:47

US3902060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Contact Made (CONTACT MADE)'	Bram Swarr (b) (4)	11 Nov 2020 21:31:47

US3902060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	11 Nov 2020 21:31:47

US3902060

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	11 Nov 2020 21:32:09

US3902060

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'I'	System	11 Nov 2020 21:32:09

US3902060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	11 Nov 2020 21:32:24

US3902060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '7 Nov 2020'	Bram Swarr (b) (4)	11 Nov 2020 21:32:24

US3902060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Contact Made (CONTACT MADE)'	Bram Swarr (b) (4)	11 Nov 2020 21:32:24

US3902060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	11 Nov 2020 21:32:24

US3902060

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	11 Nov 2020 21:32:30

US3902060

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'I'	System	11 Nov 2020 21:32:30

US3902060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	11 Nov 2020 21:33:03

US3902060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '10 Nov 2020'	Bram Swarr (b) (4)	11 Nov 2020 21:33:03

US3902060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Clinic (Clinic)'	Bram Swarr (b) (4)	11 Nov 2020 21:33:03

US3902060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'VISIT3'	System	11 Nov 2020 21:33:03

US3902060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	11 Nov 2020 21:33:43

US3902060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '10 Nov 2020'	Bram Swarr (b) (4)	11 Nov 2020 21:33:43

US3902060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '07:35'	Bram Swarr (b) (4)	11 Nov 2020 21:33:43

US3902060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered '10 Nov 2020 07:35'	System	11 Nov 2020 21:33:43

US3902060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '96.8' F	Bram Swarr (b) (4)	11 Nov 2020 21:33:43

US3902060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Oral (Oral)'	Bram Swarr (b) (4)	11 Nov 2020 21:33:43

US3902060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	11 Nov 2020 21:33:43

US3902060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '70'	Bram Swarr (b) (4)	11 Nov 2020 21:33:43

US3902060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'bpm'	System	11 Nov 2020 21:33:43

US3902060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '16'	Bram Swarr (b) (4)	11 Nov 2020 21:33:43

US3902060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'breaths/min'	System	11 Nov 2020 21:33:43

US3902060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '157'	Bram Swarr (b) (4)	11 Nov 2020 21:33:43

US3902060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'mmHg'	System	11 Nov 2020 21:33:43

US3902060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '82'	Bram Swarr (b) (4)	11 Nov 2020 21:33:43

US3902060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'mmHg'	System	11 Nov 2020 21:33:43

US3902060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Mar 2021 05:51:03

US3902060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Mar 2021 05:51:03

US3902060

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	11 Nov 2020 21:34:10

US3902060

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	11 Nov 2020 21:34:10

US3902060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	11 Nov 2020 21:34:23

US3902060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '10 Nov 2020'	Bram Swarr (b) (4)	11 Nov 2020 21:34:23

US3902060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:01

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '07:55'	Bram Swarr (b) (4)	11 Nov 2020 21:34:23

US3902060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered '10 Nov 2020 07:55'	System	11 Nov 2020 21:34:23

US3902060

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	11 Nov 2020 21:34:32

US3902060

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'I'	System	11 Nov 2020 21:34:32

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20
Data entry locked.	System	10 Sep 2020 16:33:25
User entered 'Day 64'	System	10 Sep 2020 16:33:25

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20
Data entry locked.	System	10 Sep 2020 16:33:25
User entered '10 Nov 2020 00:01'	System	10 Sep 2020 16:33:25

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20
Data entry locked.	System	10 Sep 2020 16:33:25
User entered '14 Nov 2020 23:59'	System	10 Sep 2020 16:33:25

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20
Data entry locked.	System	10 Sep 2020 16:33:25
User entered 'Day 71'	System	10 Sep 2020 16:33:25

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20
Data entry locked.	System	10 Sep 2020 16:33:25
User entered '17 Nov 2020 00:01'	System	10 Sep 2020 16:33:25

US3902060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:00:20
Data entry locked.	System	10 Sep 2020 16:33:25
User entered '21 Nov 2020 23:59'	System	10 Sep 2020 16:33:25

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[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 (45bc624b88d9d2a3)', Time: '2020-12-12T20:03:54', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'a280fded-2bc1-4aa8-9f83-3d13277f5d67'	System	13 Dec 2020 01:04:17
User entered 'No (N)'	System	13 Dec 2020 01:04:17

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Have you been exposed to someone with 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 (45bc624b88d9d2a3)', Time: '2020-12-12T20:04:03', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'a280fded-2bc1-4aa8-9f83-3d13277f5d67'	System	13 Dec 2020 01:04:17
User entered 'No (N)'	System	13 Dec 2020 01:04:17

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2020-12-12T20:04:15', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'a280fded-2bc1-4aa8-9f83-3d13277f5d67'	System	13 Dec 2020 01:04:17
User entered '12 Dec 2020 20:04:15'	System	13 Dec 2020 01:04:17

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[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 (45bc624b88d9d2a3)', Time: '2021-01-13T18:17:34', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '5af67771-bd36-48bd-a0ba-674eb7117d4b'	System	13 Jan 2021 23:17:54
User entered 'No (N)'	System	13 Jan 2021 23:17:54

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Have you been exposed to someone with 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 (45bc624b88d9d2a3)', Time: '2021-01-13T18:17:48', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '5af67771-bd36-48bd-a0ba-674eb7117d4b'	System	13 Jan 2021 23:17:54
User entered 'No (N)'	System	13 Jan 2021 23:17:54

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2021-01-13T18:17:52', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '5af67771-bd36-48bd-a0ba-674eb7117d4b'	System	13 Jan 2021 23:17:54
User entered '13 Jan 2021 18:17:52'	System	13 Jan 2021 23:17:54

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[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 (45bc624b88d9d2a3)', Time: '2021-01-16T06:48:21', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '7d2b4714-a8b6-404b-adeb-327008234341'	System	16 Jan 2021 11:48:29
User entered 'No (N)'	System	16 Jan 2021 11:48:29

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Have you been exposed to someone with 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 (45bc624b88d9d2a3)', Time: '2021-01-16T06:48:24', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '7d2b4714-a8b6-404b-adeb-327008234341'	System	16 Jan 2021 11:48:29
User entered 'No (N)'	System	16 Jan 2021 11:48:29

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2021-01-16T06:48:28', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '7d2b4714-a8b6-404b-adeb-327008234341'	System	16 Jan 2021 11:48:29
User entered '16 Jan 2021 06:48:28'	System	16 Jan 2021 11:48:29

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[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 (45bc624b88d9d2a3)', Time: '2021-01-26T07:09:40', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '76876bcc-2c79-4209-afe7-073bbe07366d'	System	26 Jan 2021 12:09:51
User entered 'No (N)'	System	26 Jan 2021 12:09:51

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Have you been exposed to someone with 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 (45bc624b88d9d2a3)', Time: '2021-01-26T07:09:46', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '76876bcc-2c79-4209-afe7-073bbe07366d'	System	26 Jan 2021 12:09:51
User entered 'No (N)'	System	26 Jan 2021 12:09:51

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2021-01-26T07:09:50', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '76876bcc-2c79-4209-afe7-073bbe07366d' User entered '26 Jan 2021 07:09:50'	System	26 Jan 2021 12:09:51
	System	26 Jan 2021 12:09:51

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[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 (45bc624b88d9d2a3)', Time: '2021-02-01T12:00:30', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '04ef7ec2-b938-4f66-afec-9c63fd341084'	System	01 Feb 2021 17:02:17
User entered 'No (N)'	System	01 Feb 2021 17:02:17

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Have you been exposed to someone with 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 (45bc624b88d9d2a3)', Time: '2021-02-01T12:00:34', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '04ef7ec2-b938-4f66-afec-9c63fd341084'	System	01 Feb 2021 17:02:17
User entered 'No (N)'	System	01 Feb 2021 17:02:17

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2021-02-01T12:00:38', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '04ef7ec2-b938-4f66-afec-9c63fd341084'	System	01 Feb 2021 17:02:17
User entered '01 Feb 2021 12:00:38'	System	01 Feb 2021 17:02:17

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[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 (45bc624b88d9d2a3)', Time: '2021-02-08T12:02:38', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '863523f4-364b-4f8e-b606-ebc37d1017bf'	System	08 Feb 2021 17:08:15
User entered 'No (N)'	System	08 Feb 2021 17:08:15

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Have you been exposed to someone with 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 (45bc624b88d9d2a3)', Time: '2021-02-08T12:02:52', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '863523f4-364b-4f8e-b606-ebc37d1017bf'	System	08 Feb 2021 17:08:15
User entered 'No (N)'	System	08 Feb 2021 17:08:15

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2021-02-08T12:02:58', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '863523f4-364b-4f8e-b606-ebc37d1017bf' User entered '08 Feb 2021 12:02:58'	System	08 Feb 2021 17:08:15

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[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 (45bc624b88d9d2a3)', Time: '2021-02-20T09:14:41-05:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '898db62a-4588-4e0c-ae72-11d0e0f4bfe7'	System	24 Feb 2021 15:42:16
User entered 'No (N)'	System	24 Feb 2021 15:42:16

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Have you been exposed to someone with 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 (45bc624b88d9d2a3)', Time: '2021-02-24T10:42:00-05:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '898db62a-4588-4e0c-ae72-11d0e0f4bfe7'	System	24 Feb 2021 15:42:16
User entered 'No (N)'	System	24 Feb 2021 15:42:16

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2021-02-24T10:42:13-05:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '898db62a-4588-4e0c-ae72-11d0e0f4bfe7'	System	24 Feb 2021 15:42:16
User entered '24 Feb 2021 10:42:13'	System	24 Feb 2021 15:42:16

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[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 (45bc624b88d9d2a3)', Time: '2021-03-07T15:42:21-05:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '147cd0ae-f3ff-4275-bbaa-ffb06b4211de' User entered 'Yes (Y)'	System	07 Mar 2021 20:43:02
	System	07 Mar 2021 20:43:02

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Have you been exposed to someone with 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 (45bc624b88d9d2a3)', Time: '2021-03-07T15:42:25-05:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '147cd0ae-f3ff-4275-bbaa-ffb06b4211de'	System	07 Mar 2021 20:43:02
User entered 'No (N)'	System	07 Mar 2021 20:43:02

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[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 (45bc624b88d9d2a3)', Time: '2021-03-07T15:42:30-05:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '147cd0ae-f3ff-4275-bbaa-ffb06b4211de'	System	07 Mar 2021 20:43:02
User entered 'No (N)'	System	07 Mar 2021 20:43:02

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[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 (45bc624b88d9d2a3)', Time: '2021-03-07T15:42:38-05:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '147cd0ae-f3ff-4275-bbaa-ffb06b4211de' User entered 'Yes (Y)'	System	07 Mar 2021 20:43:02

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Please 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 (45bc624b88d9d2a3)', Time: '2021-03-07T15:42:48-05:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '147cd0ae-f3ff-4275-bbaa-ffb06b4211de'	System	07 Mar 2021 20:43:02
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Mar 2021 20:43:02

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2021-03-07T15:42:52-05:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '147cd0ae-f3ff-4275-bbaa-ffb06b4211de' User entered '07 Mar 2021 15:42:52'	System	07 Mar 2021 20:43:02
	System	07 Mar 2021 20:43:02

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[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 (45bc624b88d9d2a3)', Time: '2021-03-31T08:34:22-04:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'c6ab02d7-4de8-4dc6-b3b1-d08493c6101e'	System	31 Mar 2021 12:34:39
User entered 'No (N)'	System	31 Mar 2021 12:34:39

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Have you been exposed to someone with 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 (45bc624b88d9d2a3)', Time: '2021-03-31T08:34:25-04:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'c6ab02d7-4de8-4dc6-b3b1-d08493c6101e'	System	31 Mar 2021 12:34:39
User entered 'No (N)'	System	31 Mar 2021 12:34:39

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2021-03-31T08:34:28-04:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'c6ab02d7-4de8-4dc6-b3b1-d08493c6101e' User entered '31 Mar 2021 08:34:28'	System	31 Mar 2021 12:34:39
	System	31 Mar 2021 12:34:39

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[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 (45bc624b88d9d2a3)', Time: '2021-04-05T12:00:29-04:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '65616612-7726-425e-bff4-45976ec9413c'	System	05 Apr 2021 16:02:32
User entered 'No (N)'	System	05 Apr 2021 16:02:32

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Have you been exposed to someone with 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 (45bc624b88d9d2a3)', Time: '2021-04-05T12:00:36-04:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '65616612-7726-425e-bff4-45976ec9413c'	System	05 Apr 2021 16:02:32
User entered 'No (N)'	System	05 Apr 2021 16:02:32

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2021-04-05T12:00:40-04:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '65616612-7726-425e-bff4-45976ec9413c' User entered '05 Apr 2021 12:00:40'	System	05 Apr 2021 16:02:32
	System	05 Apr 2021 16:02:32

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[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 (45bc624b88d9d2a3)', Time: '2021-04-11T12:48:57-04:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '6173f600-ba7d-4f35-85f2-cdf0d66e59bf'	System	11 Apr 2021 16:49:07
User entered 'No (N)'	System	11 Apr 2021 16:49:07

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Have you been exposed to someone with 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 (45bc624b88d9d2a3)', Time: '2021-04-11T12:49:01-04:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '6173f600-ba7d-4f35-85f2-cdf0d66e59bf'	System	11 Apr 2021 16:49:07
User entered 'No (N)'	System	11 Apr 2021 16:49:07

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2021-04-11T12:49:05-04:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: '6173f600-ba7d-4f35-85f2-cdf0d66e59bf'	System	11 Apr 2021 16:49:07
User entered '11 Apr 2021 12:49:05'	System	11 Apr 2021 16:49:07

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[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 (45bc624b88d9d2a3)', Time: '2021-04-17T07:39:23-04:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'a6793467-07e4-44b9-ba24-019c51f1d01d'	System	17 Apr 2021 11:39:41
User entered 'No (N)'	System	17 Apr 2021 11:39:41

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Have you been exposed to someone with 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 (45bc624b88d9d2a3)', Time: '2021-04-17T07:39:31-04:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'a6793467-07e4-44b9-ba24-019c51f1d01d'	System	17 Apr 2021 11:39:41
User entered 'No (N)'	System	17 Apr 2021 11:39:41

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2021-04-17T07:39:38-04:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'a6793467-07e4-44b9-ba24-019c51f1d01d'	System	17 Apr 2021 11:39:41
User entered '17 Apr 2021 07:39:38'	System	17 Apr 2021 11:39:41

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[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 (45bc624b88d9d2a3)', Time: '2021-04-26T12:00:43-04:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'b96ef3a4-1c32-4791-a55a-e4eec57636fa' User entered 'No (N)'	System	26 Apr 2021 16:02:45
	System	26 Apr 2021 16:02:45

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

Have you been exposed to someone with 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 (45bc624b88d9d2a3)', Time: '2021-04-26T12:00:47-04:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'b96ef3a4-1c32-4791-a55a-e4eec57636fa'	System	26 Apr 2021 16:02:45
User entered 'No (N)'	System	26 Apr 2021 16:02:45

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2021-04-26T12:00:52-04:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'b96ef3a4-1c32-4791-a55a-e4eec57636fa'	System	26 Apr 2021 16:02:45
User entered '26 Apr 2021 12:00:52'	System	26 Apr 2021 16:02:45

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 07:00:20

US3902060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:20
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 07:00:20

US3902060

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:19:01

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 06:39:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2021-03-04T04:07:16-05:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e80bc658-9cf2-429c-99d6-06ac32c6f23f'	System	04 Mar 2021 09:07:35
User entered 'No (N)'	System	04 Mar 2021 09:07:35

US3902060

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:19:01

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:39:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45bc624b88d9d2a3)', Time: '2021-03-04T04:07:31-05:00', User OID: 'PatientReportedOutcome (US3902060)', ODM File OID: 'e80bc658-9cf2-429c-99d6-06ac32c6f23f' User entered '04 Mar 2021 04:07:31'	System	04 Mar 2021 09:07:35
	System	04 Mar 2021 09:07:35

US3902060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	12 Dec 2020 14:14:30

US3902060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '11 Dec 2020'	Taylor Atkinson (b) (4)	12 Dec 2020 14:14:30

US3902060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Contact Made (CONTACT MADE)'	Taylor Atkinson (b) (4)	12 Dec 2020 14:14:30

US3902060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Taylor Atkinson (b) (4)	12 Dec 2020 14:14:30

US3902060

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	12 Dec 2020 14:15:05

US3902060

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:51:03
User entered 'I'	System	12 Dec 2020 14:15:05

US3902060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:56:59
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	12 Jan 2021 21:29:15

US3902060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:56:59
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '12 Jan 2021'	Bram Swarr (b) (4)	12 Jan 2021 21:29:15

US3902060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:56:59
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Contact Made (CONTACT MADE)'	Bram Swarr (b) (4)	12 Jan 2021 21:29:15

US3902060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:56:59
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	12 Jan 2021 21:29:15

US3902060

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:56:59
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	12 Jan 2021 21:29:23

US3902060

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:56:59
User entered 'I'	System	12 Jan 2021 21:29:23

US3902060

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:56:59
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:56
User entered 'Yes (Y)'	Bram Swarr (b) (4)	02 Mar 2021 20:03:20

US3902060

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:56:59
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:56
User entered '9 Feb 2021'	Bram Swarr (b) (4)	02 Mar 2021 20:03:20

US3902060

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:56:59
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:56
User entered 'Contact Made (CONTACT MADE)'	Bram Swarr (b) (4)	02 Mar 2021 20:03:20

US3902060

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:56:59
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:56
User entered empty.	Bram Swarr (b) (4)	02 Mar 2021 20:03:20

US3902060

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:56:59
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:56
User entered 'Yes (Y)'	Bram Swarr (b) (4)	02 Mar 2021 20:03:29

US3902060

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:56:59
User entered 'I'	System	02 Mar 2021 20:03:29

US3902060

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:07:39
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	17 Mar 2021 13:40:45

US3902060

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:07:39
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
User entered '16 Mar 2021'	Taylor Atkinson (b) (4)	17 Mar 2021 13:40:45

US3902060

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:07:39
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
User entered 'Contact Made (CONTACT MADE)'	Taylor Atkinson (b) (4)	17 Mar 2021 13:40:45

US3902060

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:07:39
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
User entered empty.	Taylor Atkinson (b) (4)	17 Mar 2021 13:40:45

US3902060

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:07:39
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	17 Mar 2021 13:40:50

US3902060

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:07:39
User entered 'I'	System	17 Mar 2021 13:40:50

US3902060

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:35
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:44:40
User entered 'Yes (Y)'	Bram Swarr (b) (4)	01 Apr 2021 14:12:09

US3902060

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:35
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:44:40
User entered '31 Mar 2021'	Bram Swarr (b) (4)	01 Apr 2021 14:12:09

US3902060

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:35
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:44:40
User entered 'Clinic (Clinic)'	Bram Swarr (b) (4)	01 Apr 2021 14:12:09

US3902060

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:35
User entered 'VISIT4'	System	01 Apr 2021 14:12:09

US3902060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:35
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:44:40
User entered 'Yes (Y)'	Bram Swarr (b) (4)	01 Apr 2021 14:13:36

US3902060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:35
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:44:40
User entered '31 Mar 2021'	Bram Swarr (b) (4)	01 Apr 2021 14:13:36

US3902060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:35
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:44:40
User entered '07:52'	Bram Swarr (b) (4)	01 Apr 2021 14:13:36

US3902060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:35
User entered '31 Mar 2021 07:52'	System	01 Apr 2021 14:13:36

US3902060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:35
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:44:40
User entered '98.3' F	Bram Swarr (b) (4)	01 Apr 2021 14:13:36

US3902060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:35
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:44:40
User entered 'Oral (Oral)'	Bram Swarr (b) (4)	01 Apr 2021 14:13:36

US3902060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:35
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:44:40
User entered empty.	Bram Swarr (b) (4)	01 Apr 2021 14:13:36

US3902060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:35
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:44:40
User entered '73'	Bram Swarr (b) (4)	01 Apr 2021 14:13:36

US3902060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:35
User entered 'bpm'	System	01 Apr 2021 14:13:36

US3902060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:35
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:44:40
User entered '16'	Bram Swarr (b) (4)	01 Apr 2021 14:13:36

US3902060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:35
User entered 'breaths/min'	System	01 Apr 2021 14:13:36

US3902060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:35
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:44:40
User entered '138'	Bram Swarr (b) (4)	01 Apr 2021 14:13:36

US3902060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:35
User entered 'mmHg'	System	01 Apr 2021 14:13:36

US3902060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:35
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:44:40
User entered '81'	Bram Swarr (b) (4)	01 Apr 2021 14:13:36

US3902060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:35
User entered 'mmHg'	System	01 Apr 2021 14:13:36

US3902060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	02 May 2021 12:10:35

US3902060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:01

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	02 May 2021 12:10:35

US3902060

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:35
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
User entered 'No (N)'	Bram Swarr (b) (4)	01 Apr 2021 14:13:52

US3902060

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:35
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
User entered empty.	Bram Swarr (b) (4)	01 Apr 2021 14:13:52

US3902060

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:35
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
User entered 'Yes (Y)'	Bram Swarr (b) (4)	01 Apr 2021 14:14:09

US3902060

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:35
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
User entered '31 Mar 2021'	Bram Swarr (b) (4)	01 Apr 2021 14:14:09

US3902060

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:35
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
User entered '08:32'	Bram Swarr (b) (4)	01 Apr 2021 14:14:09

US3902060

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:35
User entered '31 Mar 2021 08:32'	System	01 Apr 2021 14:14:09

US3902060

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:35
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
User entered 'Yes (Y)'	Bram Swarr (b) (4)	01 Apr 2021 14:14:19

US3902060

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:35
User entered 'I'	System	01 Apr 2021 14:14:19

US3902060

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

Form: Visit Date

Generated On: 10 Jun 2021 10:19:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	10 Feb 2021 19:21:07

US3902060

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

Form: Visit Date

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '9 Feb 2021'	Bram Swarr (b) (4)	10 Feb 2021 19:21:07

US3902060

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

Form: Visit Date

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Clinic (Clinic)'	Bram Swarr (b) (4)	10 Feb 2021 19:21:07

US3902060

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

Form: Visit Date

Generated On: 10 Jun 2021 10:19:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered 'UNBLND_DECIDE'	System	10 Feb 2021 19:21:07

US3902060

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

Form: Unblinding

Generated On: 10 Jun 2021 10:19:01

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '9 Feb 2021'	Bram Swarr (b) (4)	10 Feb 2021 19:20:57

US3902060

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

Form: Unblinding

Generated On: 10 Jun 2021 10:19:01

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:02:41

US3902060

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

Form: Unblinding

Generated On: 10 Jun 2021 10:19:01

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	10 Feb 2021 19:20:57

US3902060

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

Form: Unblinding

Generated On: 10 Jun 2021 10:19:01

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:02:41

US3902060

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

Form: Unblinding

Generated On: 10 Jun 2021 10:19:01

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '9 Feb 2021'	Bram Swarr (b) (4)	10 Feb 2021 19:20:57

US3902060

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

Form: Unblinding

Generated On: 10 Jun 2021 10:19:01

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'mRNA-1273 (mRNA-1273)'	Bram Swarr (b) (4)	10 Feb 2021 19:20:57

US3902060

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

Form: Unblinding

Generated On: 10 Jun 2021 10:19:01

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'mRNA-1273 (mRNA-1273)'	Bram Swarr (b) (4)	10 Feb 2021 19:20:57

US3902060

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

Form: Unblinding

Generated On: 10 Jun 2021 10:19:01

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'mRNA-1273 (mRNA-1273)'	Bram Swarr (b) (4)	10 Feb 2021 19:20:57

US3902060

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

Form: Unblinding

Generated On: 10 Jun 2021 10:19:01

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	10 Feb 2021 19:20:57

US3902060

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

Form: Unblinding

Generated On: 10 Jun 2021 10:19:01

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered empty.	System	10 Feb 2021 19:20:57

US3902060

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

Form: Unblinding

Generated On: 10 Jun 2021 10:19:01

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered empty.	System	10 Feb 2021 19:20:57

US3902060

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	10 Feb 2021 19:21:19

US3902060

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '9 Feb 2021'	Bram Swarr (b) (4)	10 Feb 2021 19:21:19

US3902060

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:01

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '10:47'	Bram Swarr (b) (4)	10 Feb 2021 19:21:19

US3902060

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered '9 Feb 2021 10:47'	System	10 Feb 2021 19:21:19

US3902060

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:19:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	10 Feb 2021 19:21:39

US3902060

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:19:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '9 Feb 2021'	Bram Swarr (b) (4)	10 Feb 2021 19:21:39

US3902060

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:19:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '10:45'	Bram Swarr (b) (4)	10 Feb 2021 19:21:39

US3902060

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:19:01

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:30:05
User entered '9 Feb 2021 10:45'	System	10 Feb 2021 19:21:39

US3902060

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:19:01

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:17:38
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:16:49
User closed query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 180, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 11:25:01
Query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 180, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'SAE has been recorded' (Site from DM).	Taylor Atkinson (b) (4)	05 Apr 2021 19:38:40
User opened query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 180, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 03:20:37
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	11 Nov 2020 21:38:20

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 16:11:29

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Aural disorders NEC, HLT: Ear disorders NEC, PT: Ear pain, LLT: Earache - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 21:42:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 21:42:37
Data point term sent to Coder	System	11 Nov 2020 21:42:24
User entered 'right earache'	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '27 Oct 2020'	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User entered empty.	System	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '30 Oct 2020'	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User entered empty.	System	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Not Related (NOT RELATED)'	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Not Related (NOT RELATED)'	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Not Applicable (NOT APPLICABLE)'	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'I'	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[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 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User entered '0'	System	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:29
User entered '1'	System	11 Nov 2020 21:41:44

US3902060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 16:11:29

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:33:40
User entered 'USA-US210-2021-mRNA-1273-P301000003'	System	09 Mar 2021 15:33:34
User entered 'New'	(b) (4), (b) (6)	09 Mar 2021 15:33:34

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Exocrine pancreas conditions, HLT: Acute and chronic pancreatitis, PT: Pancreatitis, LLT: Pancreatitis - version MedDRA\\23.0.	Coder Import (b) (4)	08 Mar 2021 23:16:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Mar 2021 23:16:49
Data point term sent to Coder	System	08 Mar 2021 23:16:15
User entered 'Pancreatitis'	Taylor Atkinson (b) (4)	08 Mar 2021 23:16:06
	(b) (4)	

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Atkinson (b) (4) (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Taylor Atkinson (b) (4) (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Taylor Atkinson (b) (4) (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Mar 2021'	Taylor Atkinson (b) (4) (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Taylor Atkinson (b) (4) (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 20:07:10
User entered 'Yes (Y)'	Taylor Atkinson (b) (4) (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Taylor Atkinson (b) (4) (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Taylor Atkinson (b) (4) (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.' Please leave query open until information is available.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 20:06:53
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.' Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 16:03:31
User entered empty.	System	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Taylor Atkinson (b) (4) (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Atkinson (b) (4) (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

Death

Audit	User	Time (GMT)
User entered '0'	Taylor Atkinson (b) (4) (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Atkinson (b) (4) (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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)	09 Mar 2021 10:52:03
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 'Subject is still actively in the hospital. Site to update when subject is discharged' (Site from System).	Taylor Atkinson (b) (4)	08 Mar 2021 23:16:34
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 Mar 2021 23:16:06
User entered '1'	Taylor Atkinson (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Mar 2021'	Taylor Atkinson (b) (4) (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 16:02:23
User entered empty.	Taylor Atkinson (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Taylor Atkinson (b) (4) (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Taylor Atkinson (b) (4) (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User entered '0'	Taylor Atkinson (b) (4) (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Atkinson (b) (4) (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Atkinson (b) (4) (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Taylor Atkinson (b) (4) (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Taylor Atkinson (b) (4) (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Taylor Atkinson (b) (4) (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

None

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Apr 2021 20:34:24
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	08 Mar 2021 23:16:06
User entered '0'	Taylor Atkinson (b) (4) (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	09 Apr 2021 20:34:24
	(b) (4)	
User entered '0'	Taylor Atkinson (b) (4)	08 Mar 2021 23:16:06
	(b) (4)	

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Atkinson (b) (4) (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 16:02:53
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Taylor Atkinson (b) (4) (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Taylor Atkinson (b) (4) (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[Narrative](#)

Audit	User	Time (GMT)
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 16:05:07
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 Mar 2021 16:03:48
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 16:02:37
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 16:02:04
User entered 'SUBJECT CONTACTED BY SITE STAFF ON 08MAR2021 AND STATED HE IS IN THE HOSPITAL WITH PANCREATITIS. STATES HE HAD ABDOMINAL PAIN ON 02MAR2021 AND WAS ADMITTED FOR WORK UP. SUBJECT STATES HE IS FEELING BETTER AND ANTICIPATED DISCHARGE TOMORROW ON 09MAR2021. SUBJECT SAYS HE FORGOT TO NOTIFY SITE. SENT SUBJECT MEDICAL RELEASE FORM TO HOME.' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	08 Mar 2021 23:17:05

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject contacted by site staff on 08Mar2021 and stated he is in the hospital with pancreatitis. States he had abdominal pain on 02Mar2021 and was admitted for work up. Subject states he is feeling better and anticipated discharge tomorrow on 09Mar2021. Subject says he forgot to notify us. Sent subject medical release form to home.'	Taylor Atkinson (b) (4) (b) (4)	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Mar 2021 23:16:06

US3902060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Mar 2021 23:16:06

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:19:01

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:17:38
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	18 Sep 2020 19:19:40

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 19:21:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 19:21:46
Data point term sent to Coder	System	18 Sep 2020 19:21:09
User entered 'loratadine'	Bram Swarr (b) (4)	18 Sep 2020 19:21:04

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:21:04

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered 'environmental allergies'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:21:04

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered '10'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:21:04

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered 'mg (mg)'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:21:04

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:21:04

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered 'as needed (PRN)'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:21:04

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:21:04

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered 'Oral (ORAL)'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:21:04

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:21:04

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:01

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'un UNK 2016'	Bram Swarr (b) (4)	18 Sep 2020 19:21:04

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:21:04

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	18 Sep 2020 19:21:04

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:21:04

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:21:04

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:21:04

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:21:04

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:21:04

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 19:22:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 19:22:47
Data point term sent to Coder	System	18 Sep 2020 19:22:11
User entered 'metformin'	Bram Swarr (b) (4)	18 Sep 2020 19:21:30

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	18 Sep 2020 19:21:30

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'diabetes'	Bram Swarr (b) (4)	18 Sep 2020 19:21:30

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered '1000'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:21:30

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered 'mg (mg)'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:21:30

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:21:30

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'twice daily (BID)'	Bram Swarr (b) (4)	18 Sep 2020 19:21:30

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:21:30

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Oral (ORAL)'	Bram Swarr (b) (4)	18 Sep 2020 19:21:30

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:21:30

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:01

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'un UNK 2012'	Bram Swarr (b) (4)	18 Sep 2020 19:21:30

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:01

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	18 Sep 2020 19:21:30

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:21:30

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:21:30

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:21:30

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Sep 2020 19:21:30

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:21:30

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 19:21:30

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 19:22:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 19:22:48
Data point term sent to Coder	System	18 Sep 2020 19:22:11
User entered 'losartan'	Bram Swarr (b) (4)	18 Sep 2020 19:22:09

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:22:09

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered 'hypertension'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:22:09

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '25'	Bram Swarr (b) (4)	18 Sep 2020 19:22:09

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered 'mg (mg)'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:22:09

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:22:09

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'once daily (QD)'	Bram Swarr (b) (4)	18 Sep 2020 19:22:09

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:22:09

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered 'Oral (ORAL)'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:22:09

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:22:09

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:01

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'un Aug 2019'	Bram Swarr (b) (4)	18 Sep 2020 19:22:09

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:22:09

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:22:09

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:22:09

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:22:09

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:22:09

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:22:09

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 19:22:09

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 19:24:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 19:24:38
Data point term sent to Coder	System	18 Sep 2020 19:23:13
User entered 'omeprazole'	Bram Swarr (b) (4)	18 Sep 2020 19:22:41

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:22:41

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'gastric reflux'	Bram Swarr (b) (4)	18 Sep 2020 19:22:41

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered '40'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:22:41

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered 'mg (mg)'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:22:41

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:22:41

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'once daily (QD)'	Bram Swarr (b) (4)	18 Sep 2020 19:22:41

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:22:41

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Oral (ORAL)'	Bram Swarr (b) (4)	18 Sep 2020 19:22:41

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:22:41

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:01

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'un UNK 2012'	Bram Swarr (b) (4)	18 Sep 2020 19:22:41

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:01

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	18 Sep 2020 19:22:41

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4)	18 Sep 2020 19:22:41

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:22:41

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	18 Sep 2020 19:22:41

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:22:41

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:22:41

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 19:22:41

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 19:24:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 19:24:38
Data point term sent to Coder	System	18 Sep 2020 19:23:14
User entered 'atorvastatin'	Bram Swarr (b) (4)	18 Sep 2020 19:23:11

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	18 Sep 2020 19:23:11

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered 'hypercholesterolemia'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:23:11

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered '20'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:23:11

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered 'mg (mg)'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:23:11

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:23:11

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'once daily (QD)'	Bram Swarr (b) (4)	18 Sep 2020 19:23:11

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:23:11

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Oral (ORAL)'	Bram Swarr (b) (4)	18 Sep 2020 19:23:11

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:23:11

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:01

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered 'un UNK 2015'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:23:11

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:01

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	18 Sep 2020 19:23:11

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:23:11

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:23:11

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	18 Sep 2020 19:23:11

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:23:11

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:23:11

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 19:23:11

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: FENOFIBRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 19:25:40
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	18 Sep 2020 19:25:40
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	18 Sep 2020 19:24:15
User entered 'fenofibrate'	Bram Swarr (b) (4)	18 Sep 2020 19:23:55

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	18 Sep 2020 19:23:55

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered 'hypertriglyceridemia'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:23:55

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '200'	Bram Swarr (b) (4)	18 Sep 2020 19:23:55

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered 'mg (mg)'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:23:55

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:23:55

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'once daily (QD)'	Bram Swarr (b) (4)	18 Sep 2020 19:23:55

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:23:55

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered 'Oral (ORAL)'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:23:55

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:23:55

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding Med History condition. Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:16:56
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding Med History condition. Please review and reconcile Con Med and Med History start dates as appropriate. ' answered with 'updated per query' (Site from DM).	Bram Swarr (b) (4)	18 Nov 2020 15:12:16
User entered 'UN UNK 2015' reason for change: Data Entry Error	Bram Swarr (b) (4)	18 Nov 2020 15:12:03
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding Med History condition. Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 02:47:54
User entered 'un UNK 2010'	Bram Swarr (b) (4)	18 Sep 2020 19:23:55

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:01

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	18 Sep 2020 19:23:55

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:23:55

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:23:55

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4) [REDACTED]	18 Sep 2020 19:23:55

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:23:55

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:23:55

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 19:23:55

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:09
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 23:02:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 23:02:35
Data point term sent to Coder	System	21 Oct 2020 23:01:23
User entered 'Tylenol'	Taylor Atkinson (b) (4)	21 Oct 2020 23:01:18

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:09
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Taylor Atkinson (b) (4)	21 Oct 2020 23:01:18

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:01

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:09
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MYALGIA is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MYALGIA did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 08:39:44
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MYALGIA is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MYALGIA did not meet the AE reporting criteria. ' answered with 'taken for solicited AE following injection, which does not meet AE reporting criteria' (Site from DM).	Bram Swarr (b) (4)	14 Jan 2021 14:36:01

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:01

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MYALGIA is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MYALGIA did not meet the AE reporting criteria. ' (Site from DM). User entered 'Myalgia'	(b) (4), (b) (6) (b) (4)	13 Jan 2021 02:50:05
	Taylor Atkinson (b) (4) (b) (4)	21 Oct 2020 23:01:18

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:09
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '1000'	Taylor Atkinson (b) (4)	21 Oct 2020 23:01:18

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:09
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'mg (mg)'	Taylor Atkinson (b) (4)	21 Oct 2020 23:01:18

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:09
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Taylor Atkinson (b) (4)	21 Oct 2020 23:01:18

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:09
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'once (ONCE)' reason for change: Data Entry Error	Bram Swarr (b) (4)	14 Jan 2021 14:36:57
User entered 'once daily (QD)'	Taylor Atkinson (b) (4)	21 Oct 2020 23:01:18

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:09
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Taylor Atkinson (b) (4)	21 Oct 2020 23:01:18

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:09
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Oral (ORAL)'	Taylor Atkinson (b) (4)	21 Oct 2020 23:01:18

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:09
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Taylor Atkinson (b) (4)	21 Oct 2020 23:01:18

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:09
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '15 Oct 2020'	Taylor Atkinson (b) (4)	21 Oct 2020 23:01:18

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:09
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Taylor Atkinson (b) (4)	21 Oct 2020 23:01:18

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:09
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Taylor Atkinson (b) (4)	21 Oct 2020 23:01:18

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:09
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '15 Oct 2020'	Taylor Atkinson (b) (4)	21 Oct 2020 23:01:18

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:09
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	21 Oct 2020 23:01:18

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:09
User entered empty.	System	14 Jan 2021 14:36:57
User entered '1'	System	21 Oct 2020 23:01:18

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:09
User entered empty.	System	14 Jan 2021 14:36:57
User entered '1'	System	21 Oct 2020 23:01:18

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:09
User entered empty.	System	14 Jan 2021 14:36:57
User entered '804 (804)'	System	21 Oct 2020 23:01:18

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:45:06
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: ERYTHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 06:32:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 06:32:53
Data point term sent to Coder	System	11 Nov 2020 21:38:15
User entered 'erythromycin'	Bram Swarr (b) (4)	11 Nov 2020 21:37:59

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:45:06
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	11 Nov 2020 21:37:59

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:45:06
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'right earache'	Bram Swarr (b) (4)	11 Nov 2020 21:37:59

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:45:06
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '250'	Bram Swarr (b) (4)	11 Nov 2020 21:37:59

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:45:06
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'mg (mg)'	Bram Swarr (b) (4)	11 Nov 2020 21:37:59

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:45:06
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	11 Nov 2020 21:37:59

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:45:06
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'once daily (QD)'	Bram Swarr (b) (4)	11 Nov 2020 21:37:59

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:45:06
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	11 Nov 2020 21:37:59

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:45:06
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'Oral (ORAL)'	Bram Swarr (b) (4)	11 Nov 2020 21:37:59

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:45:06
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered empty.	Bram Swarr (b) (4)	11 Nov 2020 21:37:59

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:45:06
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '27 Oct 2020'	Bram Swarr (b) (4)	11 Nov 2020 21:37:59

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:45:06
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '0'	Bram Swarr (b) (4)	11 Nov 2020 21:37:59

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:45:06
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	11 Nov 2020 21:37:59

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:45:06
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered '30 Oct 2020'	Bram Swarr (b) (4)	11 Nov 2020 21:37:59

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:45:06
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:04:16
User entered 'No (N)'	Bram Swarr (b) (4)	11 Nov 2020 21:37:59

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:45:06
User entered '1'	System	11 Nov 2020 21:37:59

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:45:06
User entered '1'	System	11 Nov 2020 21:37:59

US3902060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:45:06
User entered '804 (804)'	System	11 Nov 2020 21:37:59

US3902060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:19:01

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	05 Mar 2021 17:36:56
User entered 'No (N)'	Bram Swarr (b) (4)	02 Mar 2021 20:02:22

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
Un-reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:28
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:11
User entered 'USA-US210-2021-MRNA-1273-P301000003'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
User entered 'Yes (Y)'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
User entered 'No (N)'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
User entered 'No (N)'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
User entered 'Yes (Y)'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
User entered 'No (N)'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
User entered 'No (N)'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
User entered 'No (N)'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
User entered 'Murray'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
User entered 'Kimmel'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:52:25
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
User entered 'US'	System	09 Mar 2021 15:37:55

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Apr 2021 17:52:50
User entered '1'	System	09 Mar 2021 15:37:55

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
Un-reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:28
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:11
User entered 'USA-US210-2021-MRNA-1273-P301000003'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
User entered 'Yes (Y)'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
User entered 'No (N)'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
User entered 'No (N)'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
User entered 'Yes (Y)'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
User entered 'No (N)'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
User entered 'No (N)'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
User entered 'No (N)'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
User entered 'Murray'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
User entered 'Kimmel'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:52:25
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
User entered 'US'	System	09 Mar 2021 15:37:55

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Apr 2021 17:52:50
User entered '1'	System	09 Mar 2021 15:37:55

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:19:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
User entered '09/Mar/2021 07:37'	System	09 Mar 2021 15:37:55

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:19:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:52:25
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
User entered 'I'	(b) (4), (b) (6)	09 Mar 2021 15:37:55

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
Un-reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:28
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:11
User entered 'USA-US210-2021-MRNA-1273-P301000003'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
User entered 'Yes (Y)'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
User entered 'No (N)'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
User entered 'No (N)'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
User entered 'Yes (Y)'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
User entered 'No (N)'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
User entered 'No (N)'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
User entered 'No (N)'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
User entered 'Murray'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:37:38
User entered 'Kimmel'	System	09 Mar 2021 15:33:34

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:52:25
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:42:10
User entered 'US'	System	09 Mar 2021 15:37:55

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Apr 2021 17:52:50
User entered '1'	System	09 Mar 2021 15:37:55

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:19:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:44:27
User entered '12/Apr/2021 17:52'	System	12 Apr 2021 17:52:50

US3902060

Folder: SAE USA-US210-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:19:01

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.	Murray Kimmel (b) (4)	16 Apr 2021 20:44:27
User entered 'I'	(b) (4), (b) (6)	12 Apr 2021 17:52:50