

US3902020 (Prod: Synexus - Optimal Research - Melbourne)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:16:35

All time stamps listed in this document are displayed in GMT

US3902020

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

[Participant ID](#)

US3902020

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

US3902020

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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

US3902020

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

Date of Birth (MMM yyyy)	(b) (6) 1962
Age	57
Age Units	YEARS
Age (Derived)	57
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 22:02:51

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Date of Informed Consent (*dd MMM yyyy*) 2 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 22:02:51

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 22:02:51

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 22:02:51

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

Condition	SCIATICA
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: Vital Signs

Data signed: (b) (4) 19 Feb 2021 22:02:51

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	02 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	16:34 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 16:34
Height (<i>xxx.x</i>)	72 in
Weight (<i>xxx.x</i>)	340 lb
BMI (<i>xxx.x</i>)	46.20871 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 22:02:51

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 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 22:02:51

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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

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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 22:02:51

Generated On: 10 Jun 2021 10:16:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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 22:02:51

Generated On: 10 Jun 2021 10:16:35

What was the date of randomization? (dd MMM yyyy) 02 SEP 2020

What was the participant's randomization number? 145447

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 22:02:51

Generated On: 10 Jun 2021 10:16:35

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 22:02:51

Generated On: 10 Jun 2021 10:16:35

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)	02 SEP 2020
Time of assessment (00:00-23:59)	16:34 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 16:34
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 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 22:02:51

Generated On: 10 Jun 2021 10:16:35

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)	02 SEP 2020
Time of assessment (00:00-23:59)	18:50 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 18:50
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	155 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 22:02:51

Generated On: 10 Jun 2021 10:16:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 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: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

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) 2 SEP 2020

What was the treatment time? (00:00-23:59) 18:17 (24 HR)

Treatment Date and Time (derived) 2 SEP 2020 18:17

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 22:02:51

Generated On: 10 Jun 2021 10:16:35

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 SEP 2020

Collection time (00:00-23:59)

17:36 (24 HR)

Collection date and time (derived)

02 SEP 2020 17:36

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

Collection date (dd MMM yyyy)			02 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:40	02 SEP 2020 17:40
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

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 10:16:35

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 18:51

PC Open Date & Time

02 SEP 2020 18:37

PC Close Date & Time

02 SEP 2020 21:07

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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 96.7 °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	03 SEP 2020 10:16
PC Open Date & Time	02 SEP 2020 22:02
PC Close Date & Time	03 SEP 2020 11:59

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

97.1 °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

04 SEP 2020 11:31

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

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

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

97.1 °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

05 SEP 2020 12:48

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 12:11

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 12:02

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

96.8 °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

08 SEP 2020 13:01

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 18:51

PC Open Date & Time

02 SEP 2020 18:37

PC Close Date & Time

02 SEP 2020 21:07

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

03 SEP 2020 10:20

PC Open Date & Time

02 SEP 2020 22:02

PC Close Date & Time

03 SEP 2020 11:59

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

04 SEP 2020 11:31

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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 ☐

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

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

05 SEP 2020 12:48

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

06 SEP 2020 12:11

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

07 SEP 2020 12:02

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

08 SEP 2020 13:01

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 18:52
PC Open Date & Time	02 SEP 2020 18:37
PC Close Date & Time	02 SEP 2020 21:07

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 10:36
PC Open Date & Time	02 SEP 2020 22:02
PC Close Date & Time	03 SEP 2020 11:59

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

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 ☒

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 11:32
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

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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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

Yes ☐

PC Time stamp

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

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 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 12:49
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

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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US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 12:12
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

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 ☒

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EAB) (1725)

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US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 12:03
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 13:02
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3902020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3902020

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3902020

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

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

US3902020

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:02:52

Generated On: 10 Jun 2021 10:16:35

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

Visit date (dd MMM yyyy)	30 SEP 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 22:02:52

Generated On: 10 Jun 2021 10:16:35

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)	30 SEP 2020
Time of assessment (00:00-23:59)	12:48 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 12:48
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 22:02:52

Generated On: 10 Jun 2021 10:16:35

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)	30 SEP 2020
Time of assessment (00:00-23:59)	14:49 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 14:49
Temperature (xxx.x)	98.0 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)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3902020

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:02:52

Generated On: 10 Jun 2021 10:16:35

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.

US3902020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

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) 30 SEP 2020

What was the treatment time? (00:00-23:59) 14:02 (24 HR)

Treatment Date and Time (derived) 30 SEP 2020 14:02

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

US3902020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 22:02:52

Generated On: 10 Jun 2021 10:16:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	30 SEP 2020
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Collection time (00:00-23:59)	13:28 (24 HR)
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Collection date and time (derived)	30 SEP 2020 13:28
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US3902020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

Collection date (dd MMM yyyy)			30 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:30	30 SEP 2020 13:30
Nasopharyngeal Swab 2	Yes	13:30	30 SEP 2020 13:30

US3902020

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 14:47

PC Open Date & Time

30 SEP 2020 14:22

PC Close Date & Time

30 SEP 2020 16:52

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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 97.8 °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	01 OCT 2020 10:36
PC Open Date & Time	30 SEP 2020 17:47
PC Close Date & Time	01 OCT 2020 11:59

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 12:26

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 12:29

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

96.5 °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

04 OCT 2020 12:02

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

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

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

30 SEP 2020 14:48

PC Open Date & Time

30 SEP 2020 14:22

PC Close Date & Time

30 SEP 2020 16:52

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

01 OCT 2020 10:36

PC Open Date & Time

30 SEP 2020 17:47

PC Close Date & Time

01 OCT 2020 11:59

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

02 OCT 2020 12:27

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

03 OCT 2020 12:29

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

04 OCT 2020 12:02

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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 ☐

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

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 14:48
PC Open Date & Time	30 SEP 2020 14:22
PC Close Date & Time	30 SEP 2020 16:52

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 10:37
PC Open Date & Time	30 SEP 2020 17:47
PC Close Date & Time	01 OCT 2020 11:59

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

Yes ☐

PC Time stamp

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

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)

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 12:27
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

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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93 of 1835

EAB) (1725)

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 12:30
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 12:03
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

Yes ☐

PC Time stamp

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

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 ☐

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

Yes ☐

PC Time stamp

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3902020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3902020

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3902020

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3902020

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:03:14

Generated On: 10 Jun 2021 10:16:35

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

Visit date (dd MMM yyyy)	28 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT3
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US3902020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 22:03:14

Generated On: 10 Jun 2021 10:16:35

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3902020

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:03:14

Generated On: 10 Jun 2021 10:16:35

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.

US3902020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 22:03:14

Generated On: 10 Jun 2021 10:16:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	28 OCT 2020
-------------------------------	-------------

Collection time (00:00-23:59)	15:22 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	28 OCT 2020 15:22
------------------------------------	-------------------

US3902020

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:02:52

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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°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"/>

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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°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"/>

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT	DAY 78
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"/>

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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"/>

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2020 00:01
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Patient Cloud Close Date & Time	24 NOV 2020 23:59
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US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 103

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

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

15 DEC 2020 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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"/>

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 117

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

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

04 JAN 2021 20:41:51

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 138

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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°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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

23 FEB 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 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"/>

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

02 MAR 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 187

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

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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"/>

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

16 MAR 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

23 MAR 2021 09:58:26

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 208

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

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

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

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

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

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

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

06 APR 2021 12:59:17

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

12 APR 2021 17:41:51

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

17 APR 2021 22:03:38

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 17:16:24

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 MAY 2021 14:50:03
Patient Cloud Open Date & Time	30 APR 2021 00:01
Patient Cloud Close Date & Time	04 MAY 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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"/>

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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"/>

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 306

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

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

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

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

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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"/>

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 334

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

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

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

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

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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"/>

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 348

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

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

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

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

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
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Patient Cloud Close Date & Time	24 AUG 2021 23:59
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US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	14 SEP 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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="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"/>

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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"/>

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 418

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

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

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

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

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

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

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
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Patient Cloud Close Date & Time	16 NOV 2021 23:59
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US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 446

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

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

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

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

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

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

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	28 DEC 2021 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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"/>

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01
Patient Cloud Close Date & Time	18 JAN 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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"/>

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAR 2022 00:01
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Patient Cloud Close Date & Time	29 MAR 2022 23:59
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US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
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Patient Cloud Close Date & Time	26 APR 2022 23:59
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US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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"/>

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 614

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

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

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

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

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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"/>

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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="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"/>

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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"/>

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 691

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

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

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

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

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2022 00:01
Patient Cloud Close Date & Time	26 JUL 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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"/>

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Patient Cloud Open Date & Time	12 AUG 2022 00:01
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Patient Cloud Close Date & Time	16 AUG 2022 23:59
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US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Patient Cloud Open Date & Time	26 AUG 2022 00:01
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Patient Cloud Close Date & Time	30 AUG 2022 23:59
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US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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"/>

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 747

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

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

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

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

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

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

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 SEP 2022 00:01
Patient Cloud Close Date & Time	04 OCT 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3902020

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:16:35

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		10 MAR 2021 10:03:18

US3902020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3902020

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902020

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3902020

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902020

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3902020

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:02:51

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902020

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 20:42:11

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3902020

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 20:42:10

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902020

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3902020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

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

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Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

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 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

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Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3902020

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:16:35

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"/>

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Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:16:35

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) 16 Apr 2021 20:42:10

Generated On: 10 Jun 2021 10:16:35

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

Visit date (dd MMM yyyy)	10 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	UNBLND_DECIDE
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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 20:42:10

Generated On: 10 Jun 2021 10:16:35

Date of updated informed consent (dd MMM yyyy) 10 MAR 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) 10 MAR 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 _____

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 20:42:10

Generated On: 10 Jun 2021 10:16:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 MAR 2021
Collection time (00:00-23:59)	11:02 (24 HR)
Collection date and time (derived)	10 MAR 2021 11:02

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 20:42:10

Generated On: 10 Jun 2021 10:16:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	10 MAR 2021
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Collection time (00:00 - 23:59)	11:04
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Collection Date and Time (derived)	10 MAR 2021 11:04
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US3902020

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Apr 2021 20:42:10

Generated On: 10 Jun 2021 10:16:35

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

AEID	USA-US210-2021-MRNA-1273-P30 1000001
Adverse event	MYOCARDIAL INFARCTION
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)	15 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	16 FEB 2021
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)	15 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	18 FEB 2021
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 (1)

Generated On: 10 Jun 2021 10:16:35

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 type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

DURING DAY 149 SAFETY
CALL, SUBJECT STATED HE
WAS ADMITTED TO PARRISH
MEDICAL CENTER ON 2/15/2021,
DIAGNOSED AS HAVING A
MYOCARDIAL INFARCTION
AND A CARDIAC STENT
PLACED ON 16FEB2021.
SUFFERED A LOWER LUNG
INFECTION WHICH SUBJECT
WAS TOLD DUE TO
INTUBATION. DISCHARGED ON
02/18/2021 WITH MEDICATION
FOR HYPERLIPIDEMIA,
HYPERTENSION, AND LUNG
INFECTION.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

AEID	
Adverse event	HYPERLIPIDEMIA
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)	15 FEB 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 checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

AEID	
Adverse event	HYPERTENSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 FEB 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 checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

AEID

Adverse event

INFECTION LOWER LOBES OF
LUNGS

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)

16 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

24 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

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 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)	_____

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Apr 2021 20:42:10

Generated On: 10 Jun 2021 10:16:35

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 20:42:10

Generated On: 10 Jun 2021 10:16:35

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPEDEMIA

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 (1)

Data signed: (b) (4) 16 Apr 2021 20:42:10

Generated On: 10 Jun 2021 10:16:35

	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)	19 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 20:42:10

Generated On: 10 Jun 2021 10:16:35

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 20:42:10

Generated On: 10 Jun 2021 10:16:35

	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)		19 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 20:42:10

Generated On: 10 Jun 2021 10:16:35

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 20:42:10

Generated On: 10 Jun 2021 10:16:35

	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)	19 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
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) 16 Apr 2021 20:42:10

Generated On: 10 Jun 2021 10:16:35

Name of Medication BRILINTA

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 90

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) 16 Apr 2021 20:42:10

Generated On: 10 Jun 2021 10:16:35

	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)	19 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 20:42:10

Generated On: 10 Jun 2021 10:16:35

Name of Medication LEVOQUIN

Prophylaxis Yes ☐
No ☒

Indication INFECTION (LOWER LOBES OF LUNGS)

Dose per administration 750

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 20:42:10

Generated On: 10 Jun 2021 10:16:35

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	19 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Apr 2021 20:42:10

Generated On: 10 Jun 2021 10:16:35

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 23 Apr 2021 17:08:39

Generated On: 10 Jun 2021 10:16:35

SAEID	USA-US210-2021-MRNA-1273-P301000001
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

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Apr 2021 17:08:39

Generated On: 10 Jun 2021 10:16:35

SAEID	USA-US210-2021-MRNA-1273-P301000001
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)	26/FEB/2021 10:36
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

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Apr 2021 17:08:39

Generated On: 10 Jun 2021 10:16:35

SAEID	USA-US210-2021-MRNA-1273-P301000001
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)	21/APR/2021 09:01
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.	True

Audit

US3902020 (Prod: Synexus - Optimal Research - Melbourne)

US3902020

Form: Participant Creation

Generated On: 10 Jun 2021 10:16:35

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:12:55
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 15:11:59
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:11:53
User entered 'US3902020'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 20:44:40

US3902020

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	02 Sep 2020 22:24:22
	(b) (4)	

US3902020

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 20:44:41

US3902020

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[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 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Clinic (Clinic)'	Taylor Atkinson (b) (4)	02 Sep 2020 22:24:22
	(b) (4)	

US3902020

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User entered 'SCRN'	System	02 Sep 2020 22:24:22

US3902020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered (b) (6) 1962'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 20:44:42

US3902020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '57'	Taylor Atkinson (b) (4)	02 Sep 2020 22:24:36
	(b) (4)	

US3902020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User entered 'YEARS'	System	02 Sep 2020 22:24:36

US3902020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User entered '57'	System	02 Sep 2020 22:24:48

US3902020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Male (M)' reason for change: Data Entry Error	Bram Swarr (b) (4)	04 Sep 2020 14:59:45
User entered 'Female (F)'	Taylor Atkinson (b) (4)	02 Sep 2020 22:24:36
	(b) (4)	

US3902020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Taylor Atkinson (b) (4)	02 Sep 2020 22:24:36
	(b) (4)	

US3902020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'I'	Taylor Atkinson (b) (4)	02 Sep 2020 22:24:36
	(b) (4)	

US3902020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '0'	Taylor Atkinson (b) (4)	02 Sep 2020 22:24:36
	(b) (4)	

US3902020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '0'	Taylor Atkinson (b) (4)	02 Sep 2020 22:24:36
	(b) (4)	

US3902020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '0'	Taylor Atkinson (b) (4)	02 Sep 2020 22:24:36
	(b) (4)	

US3902020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '0'	Taylor Atkinson (b) (4)	02 Sep 2020 22:24:36
	(b) (4)	

US3902020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '0'	Taylor Atkinson (b) (4)	02 Sep 2020 22:24:36
	(b) (4)	

US3902020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	Taylor Atkinson (b) (4)	02 Sep 2020 22:24:36
	(b) (4)	

US3902020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '0'	Taylor Atkinson (b) (4)	02 Sep 2020 22:24:36
	(b) (4)	

US3902020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '0'	Taylor Atkinson (b) (4)	02 Sep 2020 22:24:36
	(b) (4)	

US3902020

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '2 Sep 2020'	Taylor Atkinson (b) (4)	02 Sep 2020 22:24:48
	(b) (4)	

US3902020

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User entered 'Sep 2020'	System	02 Sep 2020 22:24:48

US3902020

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User entered '2020'	System	02 Sep 2020 22:24:48

US3902020

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Amendment 3 (3)'	Taylor Atkinson (b) (4)	02 Sep 2020 22:24:48
	(b) (4)	

US3902020

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	02 Sep 2020 22:24:48
	(b) (4)	

US3902020

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	Taylor Atkinson (b) (4)	02 Sep 2020 22:24:48
	(b) (4)	

US3902020

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	Taylor Atkinson (b) (4)	02 Sep 2020 22:24:48
	(b) (4)	

US3902020

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'No (N)'	Taylor Atkinson (b) (4)	02 Sep 2020 22:24:48
	(b) (4)	

US3902020

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 20:44:41

US3902020

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User entered '1'	System	02 Sep 2020 22:24:53

US3902020

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	02 Sep 2020 22:24:53
	(b) (4)	

US3902020

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:16:35

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	Bram Swarr (b) (4)	04 Sep 2020 14:49:03

US3902020

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Morbid obesity - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 14:50:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 14:50:43
	(b) (4)	
Data point term sent to Coder	System	04 Sep 2020 14:49:45
User entered 'morbid obesity'	Bram Swarr (b) (4)	04 Sep 2020 14:49:28

US3902020

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'un UNK 2000'	Bram Swarr (b) (4)	04 Sep 2020 14:49:28

US3902020

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '0'	Bram Swarr (b) (4)	04 Sep 2020 14:49:28

US3902020

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	Bram Swarr (b) (4)	04 Sep 2020 14:49:28

US3902020

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	Bram Swarr (b) (4)	04 Sep 2020 14:49:28

US3902020

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '0'	Bram Swarr (b) (4)	04 Sep 2020 14:49:28

US3902020

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User entered 'Jan 2000'	System	04 Sep 2020 14:49:28

US3902020

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User entered '2000'	System	04 Sep 2020 14:49:28

US3902020

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User entered empty.	System	04 Sep 2020 14:49:28

US3902020

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User entered empty.	System	04 Sep 2020 14:49:28

US3902020

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Sciatica, LLT: Sciatica - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 14:50:42
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 14:50:42
	(b) (4)	
Data point term sent to Coder	System	04 Sep 2020 14:49:45
User entered 'sciatica'	Bram Swarr (b) (4)	04 Sep 2020 14:49:40

US3902020

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'un UNK 2010'	Bram Swarr (b) (4)	04 Sep 2020 14:49:40

US3902020

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '0'	Bram Swarr (b) (4)	04 Sep 2020 14:49:40

US3902020

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	Bram Swarr (b) (4)	04 Sep 2020 14:49:40

US3902020

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	Bram Swarr (b) (4)	04 Sep 2020 14:49:40

US3902020

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '0'	Bram Swarr (b) (4)	04 Sep 2020 14:49:40

US3902020

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User entered 'Jan 2010'	System	04 Sep 2020 14:49:40

US3902020

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User entered '2010'	System	04 Sep 2020 14:49:40

US3902020

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User entered empty.	System	04 Sep 2020 14:49:40

US3902020

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User entered empty.	System	04 Sep 2020 14:49:40

US3902020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	Bram Swarr (b) (4)	04 Sep 2020 14:51:09

US3902020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '02 Sep 2020'	Bram Swarr (b) (4)	04 Sep 2020 14:51:09

US3902020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '16:34'	Bram Swarr (b) (4)	04 Sep 2020 14:51:09

US3902020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User entered '02 Sep 2020 16:34'	System	04 Sep 2020 14:51:09

US3902020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '72' in	Bram Swarr (b) (4)	04 Sep 2020 14:51:09
DataPoint set to visible.	System	02 Sep 2020 22:24:53

US3902020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '340' lb reason for change: Data Entry Error	Bram Swarr (b) (4)	04 Sep 2020 14:51:24
User entered '390' lb	Bram Swarr (b) (4)	04 Sep 2020 14:51:09
DataPoint set to visible.	System	02 Sep 2020 22:24:53

US3902020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User entered '46.20871'	System	04 Sep 2020 14:51:24
User entered '53.00410'	System	04 Sep 2020 14:51:09
DataPoint set to visible.	System	02 Sep 2020 22:24:53

US3902020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User entered 'kg/m2'	System	04 Sep 2020 14:51:09
DataPoint set to visible.	System	02 Sep 2020 22:24:53

US3902020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 07:11:38
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. Thank you.' answered with 'data updaed' (Site from DM).	Katrina Carlson (b) (4)	26 Sep 2020 15:38:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Sep 2020 15:38:36
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 07:52:09
User entered '98.1' F	Bram Swarr (b) (4)	04 Sep 2020 14:51:09

US3902020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty; reason for change Data Entry Error	Katrina Carlson (b) (4)	26 Sep 2020 15:38:36
	(b) (4)	
User entered 'Oral (Oral)'	Bram Swarr (b) (4)	04 Sep 2020 14:51:09

US3902020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	Bram Swarr (b) (4)	04 Sep 2020 14:51:09

US3902020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Katrina Carlson (b) (4)	26 Sep 2020 15:38:36
User entered '74'	(b) (4)	
	Bram Swarr (b) (4)	04 Sep 2020 14:51:09

US3902020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User entered 'bpm'	System	04 Sep 2020 14:51:09

US3902020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Katrina Carlson (b) (4)	26 Sep 2020 15:38:36
User entered '16'	(b) (4)	
	Bram Swarr (b) (4)	04 Sep 2020 14:51:09

US3902020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User entered 'breaths/min'	System	04 Sep 2020 14:51:09

US3902020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Katrina Carlson (b) (4)	26 Sep 2020 15:38:36
User entered '152'	(b) (4)	
	Bram Swarr (b) (4)	04 Sep 2020 14:51:09

US3902020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User entered 'mmHg'	System	04 Sep 2020 14:51:09

US3902020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Katrina Carlson (b) (4)	26 Sep 2020 15:38:36
	(b) (4)	
User entered '79'	Bram Swarr (b) (4)	04 Sep 2020 14:51:09

US3902020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User entered 'mmHg'	System	04 Sep 2020 14:51:09

US3902020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19

US3902020

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	Bram Swarr (b) (4)	04 Sep 2020 14:54:37

US3902020

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '02 Sep 2020'	Bram Swarr (b) (4)	04 Sep 2020 14:54:37

US3902020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

[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 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'No (N)'	Bram Swarr (b) (4)	04 Sep 2020 14:58:13

US3902020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'No (N)'	Bram Swarr (b) (4)	04 Sep 2020 14:58:13

US3902020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'No (N)'	Bram Swarr (b) (4)	04 Sep 2020 14:58:13

US3902020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'No (N)'	Bram Swarr (b) (4)	04 Sep 2020 14:58:13

US3902020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'No (N)'	Bram Swarr (b) (4)	04 Sep 2020 14:58:13

US3902020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

[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 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'No (N)'	Bram Swarr (b) (4)	04 Sep 2020 14:58:13

US3902020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'No (N)'	Bram Swarr (b) (4)	04 Sep 2020 14:58:13

US3902020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'No (N)'	Bram Swarr (b) (4)	04 Sep 2020 14:58:13

US3902020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

[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 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'No (N)'	Bram Swarr (b) (4)	04 Sep 2020 14:58:13

US3902020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'No (N)'	Bram Swarr (b) (4)	04 Sep 2020 14:58:13

US3902020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'No (N)'	Bram Swarr (b) (4)	04 Sep 2020 14:58:13

US3902020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'No (N)'	Bram Swarr (b) (4)	04 Sep 2020 14:58:13

US3902020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	Bram Swarr (b) (4)	04 Sep 2020 14:58:13

US3902020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User closed query 'No Risk Identified' is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	System	26 Sep 2020 15:36:58
User opened query 'No Risk Identified' is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	System	04 Sep 2020 14:58:13
User entered '0'	Bram Swarr (b) (4)	04 Sep 2020 14:58:13

US3902020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '0'	Bram Swarr (b) (4)	04 Sep 2020 14:58:13

US3902020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '0'	Bram Swarr (b) (4)	04 Sep 2020 14:58:13

US3902020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

[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 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '0'	Bram Swarr (b) (4)	04 Sep 2020 14:58:13

US3902020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '0'	Bram Swarr (b) (4)	04 Sep 2020 14:58:13

US3902020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '1' reason for change: Data Entry Error	Katrina Carlson (b) (4)	26 Sep 2020 15:36:58
	(b) (4)	
User entered '0'	Bram Swarr (b) (4)	04 Sep 2020 14:58:13

US3902020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '0'	Bram Swarr (b) (4)	04 Sep 2020 14:58:13

US3902020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	Bram Swarr (b) (4)	04 Sep 2020 14:58:13

US3902020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	Bram Swarr (b) (4)	04 Sep 2020 15:00:27

US3902020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '02 Sep 2020'	Bram Swarr (b) (4)	04 Sep 2020 15:00:27

US3902020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[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 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Clinic (Clinic)'	Bram Swarr (b) (4)	04 Sep 2020 15:00:27

US3902020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered 'VISIT1'	System	04 Sep 2020 15:00:27

US3902020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 21:54:16

US3902020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '145447'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 21:54:16

US3902020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 21:54:16

US3902020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

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 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 07:12:13
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'data updated' (Site from DM).	Katrina Carlson (b) (4)	26 Sep 2020 15:38:12
User entered 'No (N)'	Katrina Carlson (b) (4)	26 Sep 2020 15:38:04
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 14:58:08

US3902020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

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 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'No (N)'	Katrina Carlson (b) (4)	26 Sep 2020 15:38:04

US3902020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	Katrina Carlson (b) (4)	26 Sep 2020 15:38:04

US3902020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'No (N)'	Katrina Carlson (b) (4)	26 Sep 2020 15:38:04

US3902020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'No (N)'	Katrina Carlson (b) (4)	26 Sep 2020 15:38:04

US3902020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'No (N)'	Katrina Carlson (b) (4)	26 Sep 2020 15:38:04
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:02:05
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:02:00

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 07:12:28
Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly. Thank you.' answered with 'data updated' (Site from DM).	Katrina Carlson (b) (4)	26 Sep 2020 15:39:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Sep 2020 15:38:57
User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 09:50:31
User entered '72' in	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Katrina Carlson (b) (4)	26 Sep 2020 15:38:57
User entered '340' lb	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 07:12:28
Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly. Thank you.' answered with 'data updated' (Site from DM).	Katrina Carlson (b) (4)	26 Sep 2020 15:39:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Sep 2020 15:38:57
User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 09:50:31
User entered '72' in	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Katrina Carlson (b) (4)	26 Sep 2020 15:38:57
User entered '340' lb	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User accepted default value 'Pre-Dose (PREDOSE)'	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '02 Sep 2020'	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '16:34'	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered '02 Sep 2020 16:34'	System	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '98.1' F	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Oral (Oral)'	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '74'	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered 'bpm'	System	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '16'	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered 'breaths/min'	System	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '152'	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered 'mmHg'	System	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '79'	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered 'mmHg'	System	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 07:12:28
Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly. Thank you.' answered with 'data updated' (Site from DM).	Katrina Carlson (b) (4)	26 Sep 2020 15:39:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Sep 2020 15:38:57
User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 09:50:31
User entered '72' in	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Katrina Carlson (b) (4)	26 Sep 2020 15:38:57
User entered '340' lb	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User accepted default value 'Post-Dose (POSTDOSE)'	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '02 Sep 2020'	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '18:50'	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered '02 Sep 2020 18:50'	System	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '97.0' F	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Oral (Oral)'	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '69'	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered 'bpm'	System	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '14'	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered 'breaths/min'	System	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '155'	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered 'mmHg'	System	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '85'	Bram Swarr (b) (4)	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered 'mmHg'	System	04 Sep 2020 15:04:22

US3902020

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	Bram Swarr (b) (4)	04 Sep 2020 15:04:35

US3902020

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '02 Sep 2020'	Bram Swarr (b) (4)	04 Sep 2020 15:04:35

US3902020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	02 Sep 2020 22:25:24

US3902020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	Taylor Atkinson (b) (4)	02 Sep 2020 22:25:24

US3902020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

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 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	Taylor Atkinson (b) (4)	02 Sep 2020 22:25:24

US3902020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 22:25:24

US3902020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '2 Sep 2020'	Taylor Atkinson (b) (4)	02 Sep 2020 22:25:24

US3902020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '18:17'	Taylor Atkinson (b) (4)	02 Sep 2020 22:25:24

US3902020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered '2 Sep 2020 18:17'	System	02 Sep 2020 22:25:24

US3902020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Left Arm (LEFT ARM)'	Taylor Atkinson (b) (4)	02 Sep 2020 22:25:24

US3902020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered 'ONCE'	System	02 Sep 2020 22:25:24

US3902020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 22:25:24

US3902020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	Bram Swarr (b) (4)	04 Sep 2020 15:05:47

US3902020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '02 Sep 2020'	Bram Swarr (b) (4)	04 Sep 2020 15:05:47

US3902020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '17:36'	Bram Swarr (b) (4)	04 Sep 2020 15:05:47

US3902020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered '02 Sep 2020 17:36'	System	04 Sep 2020 15:05:47

US3902020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:16:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '02 Sep 2020'	Bram Swarr (b) (4)	04 Sep 2020 15:06:06

US3902020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Bram Swarr (b) (4)	04 Sep 2020 15:06:06

US3902020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	Bram Swarr (b) (4)	04 Sep 2020 15:06:06

US3902020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '17:40'	Bram Swarr (b) (4)	04 Sep 2020 15:06:06

US3902020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered '02 Sep 2020 17:40'	System	04 Sep 2020 15:06:06

US3902020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Bram Swarr (b) (4)	04 Sep 2020 15:06:06

US3902020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 11:53:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Sep 2020 11:53:09
User entered 'No (N)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	09 Sep 2020 11:53:09
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 15:06:06
User entered empty.	Bram Swarr (b) (4)	04 Sep 2020 15:06:06

US3902020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	Bram Swarr (b) (4)	04 Sep 2020 15:06:06

US3902020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered empty.	System	04 Sep 2020 15:06:06

US3902020

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	Bram Swarr (b) (4)	04 Sep 2020 15:06:24

US3902020

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered 'I'	System	04 Sep 2020 15:06:24

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	02 Sep 2020 22:25:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-02T18:50:24', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'e9823735-638f-49e6-b6de-0edd169a3c50'	System	02 Sep 2020 22:51:06
User entered 'Yes (Y)'	System	02 Sep 2020 22:51:06

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-02T18:50:48', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'e9823735-638f-49e6-b6de-0edd169a3c50'	System	02 Sep 2020 22:51:06
User entered '97.0'	System	02 Sep 2020 22:51:06

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-02T18:50:53', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'e9823735-638f-49e6-b6de-0edd169a3c50'	System	02 Sep 2020 22:51:06
User entered 'No (N)'	System	02 Sep 2020 22:51:06

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-02T18:51:03', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'e9823735-638f-49e6-b6de-0edd169a3c50'	System	02 Sep 2020 22:51:06
User entered '02 Sep 2020 18:51'	System	02 Sep 2020 22:51:06

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '02 Sep 2020 18:37'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '02 Sep 2020 21:07'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	02 Sep 2020 22:25:24
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-03T10:15:05', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '03abff62-8a0e-41c9-9741-0a574d67a082'	System	03 Sep 2020 14:16:38
User entered 'Yes (Y)'	System	03 Sep 2020 14:16:38

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-03T10:16:25', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '03abff62-8a0e-41c9-9741-0a574d67a082'	System	03 Sep 2020 14:16:38
User entered '96.7'	System	03 Sep 2020 14:16:38

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-03T10:16:29', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '03abff62-8a0e-41c9-9741-0a574d67a082'	System	03 Sep 2020 14:16:38
User entered 'No (N)'	System	03 Sep 2020 14:16:38

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-03T10:16:36', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '03abff62-8a0e-41c9-9741-0a574d67a082'	System	03 Sep 2020 14:16:38
User entered '03 Sep 2020 10:16'	System	03 Sep 2020 14:16:38

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '02 Sep 2020 22:02'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	02 Sep 2020 22:25:24
User entered 'Day 2'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-04T11:30:28', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '7d6f8244-e8d0-4ec6-a4f3-c9472e041937'	System	04 Sep 2020 15:31:15
User entered 'Yes (Y)'	System	04 Sep 2020 15:31:15

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-04T11:30:47', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '7d6f8244-e8d0-4ec6-a4f3-c9472e041937'	System	04 Sep 2020 15:31:15
User entered '97.1'	System	04 Sep 2020 15:31:15

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-04T11:31:01', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '7d6f8244-e8d0-4ec6-a4f3-c9472e041937'	System	04 Sep 2020 15:31:15
User entered 'No (N)'	System	04 Sep 2020 15:31:15

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-04T11:31:12', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '7d6f8244-e8d0-4ec6-a4f3-c9472e041937'	System	04 Sep 2020 15:31:15
User entered '04 Sep 2020 11:31'	System	04 Sep 2020 15:31:15

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	02 Sep 2020 22:25:24
User entered 'Day 3'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	02 Sep 2020 22:25:24
User entered 'Day 4'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-05T12:47:53', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '7701c821-d4a2-4ba3-83e9-2964f78223af'	System	05 Sep 2020 16:48:11
User entered 'Yes (Y)'	System	05 Sep 2020 16:48:11

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-05T12:48:03', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '7701c821-d4a2-4ba3-83e9-2964f78223af'	System	05 Sep 2020 16:48:11
User entered '97.1'	System	05 Sep 2020 16:48:11

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-05T12:48:07', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '7701c821-d4a2-4ba3-83e9-2964f78223af'	System	05 Sep 2020 16:48:11
User entered 'No (N)'	System	05 Sep 2020 16:48:11

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-05T12:48:09', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '7701c821-d4a2-4ba3-83e9-2964f78223af'	System	05 Sep 2020 16:48:11
User entered '05 Sep 2020 12:48'	System	05 Sep 2020 16:48:11

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	02 Sep 2020 22:25:24
User entered 'Day 5'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-06T12:11:21', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '1975be2a-7b31-4568-bbf2-e1745fa888da'	System	06 Sep 2020 16:11:35
User entered 'Yes (Y)'	System	06 Sep 2020 16:11:35

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-06T12:11:27', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '1975be2a-7b31-4568-bbf2-e1745fa888da'	System	06 Sep 2020 16:11:35
User entered '97.0'	System	06 Sep 2020 16:11:35

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-06T12:11:30', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '1975be2a-7b31-4568-bbf2-e1745fa888da'	System	06 Sep 2020 16:11:35
User entered 'No (N)'	System	06 Sep 2020 16:11:35

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-06T12:11:33', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '1975be2a-7b31-4568-bbf2-e1745fa888da'	System	06 Sep 2020 16:11:35
User entered '06 Sep 2020 12:11'	System	06 Sep 2020 16:11:35

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	02 Sep 2020 22:25:24
User entered 'Day 6'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-07T12:01:43', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'd2e4f915-4c25-4a8a-94a0-a9abcc11b8f7'	System	07 Sep 2020 16:02:51
User entered 'Yes (Y)'	System	07 Sep 2020 16:02:51

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-07T12:01:48', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'd2e4f915-4c25-4a8a-94a0-a9abcc11b8f7'	System	07 Sep 2020 16:02:51
User entered '97.0'	System	07 Sep 2020 16:02:51

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-07T12:02:21', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'd2e4f915-4c25-4a8a-94a0-a9abcc11b8f7'	System	07 Sep 2020 16:02:51
User entered 'No (N)'	System	07 Sep 2020 16:02:51

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-07T12:02:24', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'd2e4f915-4c25-4a8a-94a0-a9abcc11b8f7'	System	07 Sep 2020 16:02:51
User entered '07 Sep 2020 12:02'	System	07 Sep 2020 16:02:51

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	02 Sep 2020 22:25:24
User entered 'Day 7'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-08T13:00:57', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'c0b74585-dd43-4394-94a0-8987e6ec50c0'	System	08 Sep 2020 17:02:40
User entered 'Yes (Y)'	System	08 Sep 2020 17:02:40

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-08T13:01:02', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'c0b74585-dd43-4394-94a0-8987e6ec50c0'	System	08 Sep 2020 17:02:40
User entered '96.8'	System	08 Sep 2020 17:02:40

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-08T13:01:07', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'c0b74585-dd43-4394-94a0-8987e6ec50c0'	System	08 Sep 2020 17:02:40
User entered 'No (N)'	System	08 Sep 2020 17:02:40

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-08T13:01:29', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'c0b74585-dd43-4394-94a0-8987e6ec50c0'	System	08 Sep 2020 17:02:40
User entered '08 Sep 2020 13:01'	System	08 Sep 2020 17:02:40

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	02 Sep 2020 22:25:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-02T18:51:30', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '62397888-41b5-45f0-9c4a-01c9c712be82'	System	02 Sep 2020 22:51:51
User entered 'None (1)'	System	02 Sep 2020 22:51:51

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-02T18:51:33', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '62397888-41b5-45f0-9c4a-01c9c712be82'	System	02 Sep 2020 22:51:51
User entered 'No (N)'	System	02 Sep 2020 22:51:51

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-02T18:51:36', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '62397888-41b5-45f0-9c4a-01c9c712be82'	System	02 Sep 2020 22:51:51
User entered 'No (N)'	System	02 Sep 2020 22:51:51

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-02T18:51:44', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '62397888-41b5-45f0-9c4a-01c9c712be82'	System	02 Sep 2020 22:51:51
User entered 'None (1)'	System	02 Sep 2020 22:51:51

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-02T18:51:48', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '62397888-41b5-45f0-9c4a-01c9c712be82'	System	02 Sep 2020 22:51:51
User entered '02 Sep 2020 18:51'	System	02 Sep 2020 22:51:51

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '02 Sep 2020 18:37'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '02 Sep 2020 21:07'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	02 Sep 2020 22:25:24
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-03T10:16:55', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '98cdae06-3fba-4218-920c-6193f6587975'	System	03 Sep 2020 14:20:10
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 14:20:10

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-03T10:16:59', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '98cdae06-3fba-4218-920c-6193f6587975'	System	03 Sep 2020 14:20:10
User entered 'No (N)'	System	03 Sep 2020 14:20:10

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-03T10:17:02', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '98cdae06-3fba-4218-920c-6193f6587975'	System	03 Sep 2020 14:20:10
User entered 'No (N)'	System	03 Sep 2020 14:20:10

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-03T10:17:36', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '98cdae06-3fba-4218-920c-6193f6587975'	System	03 Sep 2020 14:20:10
User entered 'None (1)'	System	03 Sep 2020 14:20:10

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-03T10:20:07', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '98cdae06-3fba-4218-920c-6193f6587975'	System	03 Sep 2020 14:20:10
User entered '03 Sep 2020 10:20'	System	03 Sep 2020 14:20:10

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '02 Sep 2020 22:02'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	02 Sep 2020 22:25:24
User entered 'Day 2'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-04T11:31:28', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '5d48a1ef-9604-48cf-8b08-cf5b6e0910fc'	System	04 Sep 2020 15:31:47
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 15:31:47

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-04T11:31:32', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '5d48a1ef-9604-48cf-8b08-cf5b6e0910fc'	System	04 Sep 2020 15:31:47
User entered 'No (N)'	System	04 Sep 2020 15:31:47

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-04T11:31:35', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '5d48a1ef-9604-48cf-8b08-cf5b6e0910fc'	System	04 Sep 2020 15:31:47
User entered 'No (N)'	System	04 Sep 2020 15:31:47

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-04T11:31:39', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '5d48a1ef-9604-48cf-8b08-cf5b6e0910fc'	System	04 Sep 2020 15:31:47
User entered 'None (1)'	System	04 Sep 2020 15:31:47

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-04T11:31:43', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '5d48a1ef-9604-48cf-8b08-cf5b6e0910fc'	System	04 Sep 2020 15:31:47
User entered '04 Sep 2020 11:31'	System	04 Sep 2020 15:31:47

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	02 Sep 2020 22:25:24
User entered 'Day 3'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	02 Sep 2020 22:25:24
User entered 'Day 4'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-05T12:48:15', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '98aa9e36-d423-43cb-be8c-98067f2422b8'	System	05 Sep 2020 16:48:49
User entered 'None (1)'	System	05 Sep 2020 16:48:49

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-05T12:48:19', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '98aa9e36-d423-43cb-be8c-98067f2422b8'	System	05 Sep 2020 16:48:49
User entered 'No (N)'	System	05 Sep 2020 16:48:49

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-05T12:48:26', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '98aa9e36-d423-43cb-be8c-98067f2422b8'	System	05 Sep 2020 16:48:49
User entered 'No (N)'	System	05 Sep 2020 16:48:49

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-05T12:48:44', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '98aa9e36-d423-43cb-be8c-98067f2422b8'	System	05 Sep 2020 16:48:49
User entered 'None (1)'	System	05 Sep 2020 16:48:49

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-05T12:48:47', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '98aa9e36-d423-43cb-be8c-98067f2422b8'	System	05 Sep 2020 16:48:49
User entered '05 Sep 2020 12:48'	System	05 Sep 2020 16:48:49

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	02 Sep 2020 22:25:24
User entered 'Day 5'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-06T12:11:38', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'c3a5991c-e383-496a-b56f-d2e78a4dad7d'	System	06 Sep 2020 16:11:54
User entered 'None (1)'	System	06 Sep 2020 16:11:54

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-06T12:11:41', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'c3a5991c-e383-496a-b56f-d2e78a4dad7d'	System	06 Sep 2020 16:11:54
User entered 'No (N)'	System	06 Sep 2020 16:11:54

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-06T12:11:44', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'c3a5991c-e383-496a-b56f-d2e78a4dad7d'	System	06 Sep 2020 16:11:54
User entered 'No (N)'	System	06 Sep 2020 16:11:54

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-06T12:11:46', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'c3a5991c-e383-496a-b56f-d2e78a4dad7d'	System	06 Sep 2020 16:11:54
User entered 'None (1)'	System	06 Sep 2020 16:11:54

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-06T12:11:48', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'c3a5991c-e383-496a-b56f-d2e78a4dad7d'	System	06 Sep 2020 16:11:54
User entered '06 Sep 2020 12:11'	System	06 Sep 2020 16:11:54

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	02 Sep 2020 22:25:24
User entered 'Day 6'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-07T12:02:30', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '371529be-3cb3-4c2e-bf1f-a8da9b6017b8'	System	07 Sep 2020 16:03:07
User entered 'None (1)'	System	07 Sep 2020 16:03:07

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-07T12:02:32', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '371529be-3cb3-4c2e-bf1f-a8da9b6017b8'	System	07 Sep 2020 16:03:07
User entered 'No (N)'	System	07 Sep 2020 16:03:07

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-07T12:02:35', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '371529be-3cb3-4c2e-bf1f-a8da9b6017b8'	System	07 Sep 2020 16:03:07
User entered 'No (N)'	System	07 Sep 2020 16:03:07

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-07T12:02:37', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '371529be-3cb3-4c2e-bf1f-a8da9b6017b8'	System	07 Sep 2020 16:03:07
User entered 'None (1)'	System	07 Sep 2020 16:03:07

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-07T12:02:42', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '371529be-3cb3-4c2e-bf1f-a8da9b6017b8'	System	07 Sep 2020 16:03:07
User entered '07 Sep 2020 12:02'	System	07 Sep 2020 16:03:07

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	02 Sep 2020 22:25:24
User entered 'Day 7'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-08T13:01:35', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '40b9c1f5-049b-4167-a12d-2ccff4fdf72d'	System	08 Sep 2020 17:03:12
User entered 'None (1)'	System	08 Sep 2020 17:03:12

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-08T13:01:39', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '40b9c1f5-049b-4167-a12d-2ccff4fdf72d'	System	08 Sep 2020 17:03:12
User entered 'No (N)'	System	08 Sep 2020 17:03:12

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-08T13:01:41', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '40b9c1f5-049b-4167-a12d-2ccff4fdf72d'	System	08 Sep 2020 17:03:12
User entered 'No (N)'	System	08 Sep 2020 17:03:12

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-08T13:01:45', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '40b9c1f5-049b-4167-a12d-2ccff4fdf72d'	System	08 Sep 2020 17:03:12
User entered 'None (1)'	System	08 Sep 2020 17:03:12

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-08T13:01:48', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '40b9c1f5-049b-4167-a12d-2ccff4fdf72d'	System	08 Sep 2020 17:03:12
User entered '08 Sep 2020 13:01'	System	08 Sep 2020 17:03:12

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	02 Sep 2020 22:25:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-02T18:51:53', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'a21fb7d5-12c6-4310-b706-f27e8b8debb6'	System	02 Sep 2020 22:52:31
User entered 'None (0)'	System	02 Sep 2020 22:52:31

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-02T18:51:57', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'a21fb7d5-12c6-4310-b706-f27e8b8debb6'	System	02 Sep 2020 22:52:31
User entered 'None (0)'	System	02 Sep 2020 22:52:31

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-02T18:52:01', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'a21fb7d5-12c6-4310-b706-f27e8b8debb6'	System	02 Sep 2020 22:52:31
User entered 'None (0)'	System	02 Sep 2020 22:52:31

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-02T18:52:13', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'a21fb7d5-12c6-4310-b706-f27e8b8debb6'	System	02 Sep 2020 22:52:31
User entered 'None (0)'	System	02 Sep 2020 22:52:31

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-02T18:52:18', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'a21fb7d5-12c6-4310-b706-f27e8b8debb6'	System	02 Sep 2020 22:52:31
User entered 'None (0)'	System	02 Sep 2020 22:52:31

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-02T18:52:20', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'a21fb7d5-12c6-4310-b706-f27e8b8debb6'	System	02 Sep 2020 22:52:31
User entered 'None (0)'	System	02 Sep 2020 22:52:31

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-02T18:52:25', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'a21fb7d5-12c6-4310-b706-f27e8b8debb6'	System	02 Sep 2020 22:52:31
User entered 'No (N)'	System	02 Sep 2020 22:52:31

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-02T18:52:28', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'a21fb7d5-12c6-4310-b706-f27e8b8debb6'	System	02 Sep 2020 22:52:31
User entered '02 Sep 2020 18:52'	System	02 Sep 2020 22:52:31

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '02 Sep 2020 18:37'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '02 Sep 2020 21:07'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	02 Sep 2020 22:25:24
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-03T10:20:18', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '56ed9475-bc19-4618-bfee-566bd968090b'	System	03 Sep 2020 14:36:38
User entered 'None (0)'	System	03 Sep 2020 14:36:38

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-03T10:20:33', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '56ed9475-bc19-4618-bfee-566bd968090b'	System	03 Sep 2020 14:36:38
User entered 'None (0)'	System	03 Sep 2020 14:36:38

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-03T10:20:39', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '56ed9475-bc19-4618-bfee-566bd968090b'	System	03 Sep 2020 14:36:38
User entered 'None (0)'	System	03 Sep 2020 14:36:38

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-03T10:20:43', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '56ed9475-bc19-4618-bfee-566bd968090b'	System	03 Sep 2020 14:36:38
User entered 'None (0)'	System	03 Sep 2020 14:36:38

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-03T10:20:48', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '56ed9475-bc19-4618-bfee-566bd968090b'	System	03 Sep 2020 14:36:38
User entered 'None (0)'	System	03 Sep 2020 14:36:38

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-03T10:36:23', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '56ed9475-bc19-4618-bfee-566bd968090b'	System	03 Sep 2020 14:36:38
User entered 'None (0)'	System	03 Sep 2020 14:36:38

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-03T10:36:27', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '56ed9475-bc19-4618-bfee-566bd968090b'	System	03 Sep 2020 14:36:38
User entered 'No (N)'	System	03 Sep 2020 14:36:38

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-03T10:36:34', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '56ed9475-bc19-4618-bfee-566bd968090b'	System	03 Sep 2020 14:36:38
User entered '03 Sep 2020 10:36'	System	03 Sep 2020 14:36:38

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '02 Sep 2020 22:02'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	02 Sep 2020 22:25:24
User entered 'Day 2'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-04T11:31:51', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '54d1d5e7-1f36-4be9-9fc9-2681d2fededd'	System	04 Sep 2020 15:32:14
User entered 'None (0)'	System	04 Sep 2020 15:32:14

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-04T11:31:53', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '54d1d5e7-1f36-4be9-9fc9-2681d2fededd'	System	04 Sep 2020 15:32:14
User entered 'None (0)'	System	04 Sep 2020 15:32:14

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-04T11:31:55', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '54d1d5e7-1f36-4be9-9fc9-2681d2feddd'	System	04 Sep 2020 15:32:14
User entered 'None (0)'	System	04 Sep 2020 15:32:14

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-04T11:31:57', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '54d1d5e7-1f36-4be9-9fc9-2681d2feddd'	System	04 Sep 2020 15:32:14
User entered 'None (0)'	System	04 Sep 2020 15:32:14

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-04T11:32:01', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '54d1d5e7-1f36-4be9-9fc9-2681d2feddd'	System	04 Sep 2020 15:32:14
User entered 'None (0)'	System	04 Sep 2020 15:32:14

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-04T11:32:04', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '54d1d5e7-1f36-4be9-9fc9-2681d2fededd'	System	04 Sep 2020 15:32:14
User entered 'None (0)'	System	04 Sep 2020 15:32:14

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-04T11:32:08', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '54d1d5e7-1f36-4be9-9fc9-2681d2feddd'	System	04 Sep 2020 15:32:14
User entered 'No (N)'	System	04 Sep 2020 15:32:14

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-04T11:32:10', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '54d1d5e7-1f36-4be9-9fc9-2681d2fededd'	System	04 Sep 2020 15:32:14
User entered '04 Sep 2020 11:32'	System	04 Sep 2020 15:32:14

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	02 Sep 2020 22:25:24
User entered 'Day 3'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	02 Sep 2020 22:25:24
User entered 'Day 4'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-05T12:48:51', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'cbc2df70-ae57-4c57-94cc-f2b4bfd20e7f'	System	05 Sep 2020 16:49:10
User entered 'None (0)'	System	05 Sep 2020 16:49:10

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-05T12:48:54', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'cbc2df70-ae57-4c57-94cc-f2b4bfd20e7f'	System	05 Sep 2020 16:49:10
User entered 'None (0)'	System	05 Sep 2020 16:49:10

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-05T12:48:56', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'cbc2df70-ae57-4c57-94cc-f2b4bfd20e7f'	System	05 Sep 2020 16:49:10
User entered 'None (0)'	System	05 Sep 2020 16:49:10

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-05T12:48:58', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'cbc2df70-ae57-4c57-94cc-f2b4bfd20e7f'	System	05 Sep 2020 16:49:10
User entered 'None (0)'	System	05 Sep 2020 16:49:10

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-05T12:49:00', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'cbc2df70-ae57-4c57-94cc-f2b4bfd20e7f'	System	05 Sep 2020 16:49:10
User entered 'None (0)'	System	05 Sep 2020 16:49:10

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-05T12:49:02', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'cbc2df70-ae57-4c57-94cc-f2b4bfd20e7f'	System	05 Sep 2020 16:49:10
User entered 'None (0)'	System	05 Sep 2020 16:49:10

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-05T12:49:05', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'cbc2df70-ae57-4c57-94cc-f2b4bfd20e7f'	System	05 Sep 2020 16:49:10
User entered 'No (N)'	System	05 Sep 2020 16:49:10

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-05T12:49:07', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'cbc2df70-ae57-4c57-94cc-f2b4bfd20e7f'	System	05 Sep 2020 16:49:10
User entered '05 Sep 2020 12:49'	System	05 Sep 2020 16:49:10

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	02 Sep 2020 22:25:24
User entered 'Day 5'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-06T12:11:52', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'a7a0ee3f-fe35-4252-8118-b8c3c51e21c2'	System	06 Sep 2020 16:12:09
User entered 'None (0)'	System	06 Sep 2020 16:12:09

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-06T12:11:54', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'a7a0ee3f-fe35-4252-8118-b8c3c51e21c2'	System	06 Sep 2020 16:12:09
User entered 'None (0)'	System	06 Sep 2020 16:12:09

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-06T12:11:55', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'a7a0ee3f-fe35-4252-8118-b8c3c51e21c2'	System	06 Sep 2020 16:12:09
User entered 'None (0)'	System	06 Sep 2020 16:12:09

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-06T12:11:57', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'a7a0ee3f-fe35-4252-8118-b8c3c51e21c2'	System	06 Sep 2020 16:12:09
User entered 'None (0)'	System	06 Sep 2020 16:12:09

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-06T12:11:59', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'a7a0ee3f-fe35-4252-8118-b8c3c51e21c2'	System	06 Sep 2020 16:12:09
User entered 'None (0)'	System	06 Sep 2020 16:12:09

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-06T12:12:01', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'a7a0ee3f-fe35-4252-8118-b8c3c51e21c2'	System	06 Sep 2020 16:12:09
User entered 'None (0)'	System	06 Sep 2020 16:12:09

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-06T12:12:03', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'a7a0ee3f-fe35-4252-8118-b8c3c51e21c2'	System	06 Sep 2020 16:12:09
User entered 'No (N)'	System	06 Sep 2020 16:12:09

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-06T12:12:05', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'a7a0ee3f-fe35-4252-8118-b8c3c51e21c2'	System	06 Sep 2020 16:12:09
User entered '06 Sep 2020 12:12'	System	06 Sep 2020 16:12:09

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	02 Sep 2020 22:25:24
User entered 'Day 6'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-07T12:02:50', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '3f8ca881-0f02-4478-be5b-ca45a3d52c39'	System	07 Sep 2020 16:03:23
User entered 'None (0)'	System	07 Sep 2020 16:03:23

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-07T12:02:53', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '3f8ca881-0f02-4478-be5b-ca45a3d52c39'	System	07 Sep 2020 16:03:23
User entered 'None (0)'	System	07 Sep 2020 16:03:23

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-07T12:02:54', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '3f8ca881-0f02-4478-be5b-ca45a3d52c39'	System	07 Sep 2020 16:03:23
User entered 'None (0)'	System	07 Sep 2020 16:03:23

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-07T12:02:56', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '3f8ca881-0f02-4478-be5b-ca45a3d52c39'	System	07 Sep 2020 16:03:23
User entered 'None (0)'	System	07 Sep 2020 16:03:23

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-07T12:02:57', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '3f8ca881-0f02-4478-be5b-ca45a3d52c39'	System	07 Sep 2020 16:03:23
User entered 'None (0)'	System	07 Sep 2020 16:03:23

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-07T12:02:59', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '3f8ca881-0f02-4478-be5b-ca45a3d52c39'	System	07 Sep 2020 16:03:23
User entered 'None (0)'	System	07 Sep 2020 16:03:23

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-07T12:03:01', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '3f8ca881-0f02-4478-be5b-ca45a3d52c39'	System	07 Sep 2020 16:03:23
User entered 'No (N)'	System	07 Sep 2020 16:03:23

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-07T12:03:03', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '3f8ca881-0f02-4478-be5b-ca45a3d52c39'	System	07 Sep 2020 16:03:23
User entered '07 Sep 2020 12:03'	System	07 Sep 2020 16:03:23

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	02 Sep 2020 22:25:24
User entered 'Day 7'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-08T13:01:53', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '9313f2e2-a5b4-4513-9c4b-a8e92f45b728'	System	08 Sep 2020 17:03:44
User entered 'None (0)'	System	08 Sep 2020 17:03:44

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-08T13:01:56', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '9313f2e2-a5b4-4513-9c4b-a8e92f45b728'	System	08 Sep 2020 17:03:44
User entered 'None (0)'	System	08 Sep 2020 17:03:44

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-08T13:02:06', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '9313f2e2-a5b4-4513-9c4b-a8e92f45b728'	System	08 Sep 2020 17:03:44
User entered 'None (0)'	System	08 Sep 2020 17:03:44

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-08T13:02:08', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '9313f2e2-a5b4-4513-9c4b-a8e92f45b728'	System	08 Sep 2020 17:03:44
User entered 'None (0)'	System	08 Sep 2020 17:03:44

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-08T13:02:11', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '9313f2e2-a5b4-4513-9c4b-a8e92f45b728'	System	08 Sep 2020 17:03:44
User entered 'None (0)'	System	08 Sep 2020 17:03:44

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-08T13:02:12', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '9313f2e2-a5b4-4513-9c4b-a8e92f45b728'	System	08 Sep 2020 17:03:44
User entered 'None (0)'	System	08 Sep 2020 17:03:44

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-08T13:02:15', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '9313f2e2-a5b4-4513-9c4b-a8e92f45b728'	System	08 Sep 2020 17:03:44
User entered 'No (N)'	System	08 Sep 2020 17:03:44

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-08T13:02:17', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '9313f2e2-a5b4-4513-9c4b-a8e92f45b728'	System	08 Sep 2020 17:03:44
User entered '08 Sep 2020 13:02'	System	08 Sep 2020 17:03:44

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 22:25:24

US3902020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 22:25:24

US3902020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 20:29:41

US3902020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '9 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 20:29:41

US3902020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Sep 2020 20:29:41

US3902020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 20:29:41

US3902020

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 20:29:47

US3902020

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered 'I'	System	16 Sep 2020 20:29:47

US3902020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 20:30:00

US3902020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '16 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 20:30:00

US3902020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Sep 2020 20:30:00

US3902020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 20:30:00

US3902020

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 20:30:08

US3902020

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered 'I'	System	16 Sep 2020 20:30:08

US3902020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 16:48:56

US3902020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 16:48:56

US3902020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Sep 2020 16:48:56

US3902020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 16:48:56

US3902020

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 16:49:08

US3902020

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered 'I'	System	24 Sep 2020 16:49:08

US3902020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 15:50:05

US3902020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '30 Sep 2020'	(b) (4), (b) (6)	06 Oct 2020 15:50:05

US3902020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[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 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	06 Oct 2020 15:50:05

US3902020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User entered 'VISIT2'	System	06 Oct 2020 15:50:05

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '30 Sep 2020'	(b) (4), (b) (6)	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '12:48'	(b) (4), (b) (6)	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User entered '30 Sep 2020 12:48'	System	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '98.8' F	(b) (4), (b) (6)	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '77'	(b) (4), (b) (6)	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User entered 'bpm'	System	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '18'	(b) (4), (b) (6)	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User entered 'breaths/min'	System	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '123'	(b) (4), (b) (6)	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User entered 'mmHg'	System	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '78'	(b) (4), (b) (6)	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User entered 'mmHg'	System	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '30 Sep 2020'	(b) (4), (b) (6)	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '14:49'	(b) (4), (b) (6)	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User entered '30 Sep 2020 14:49'	System	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '98.0' F	(b) (4), (b) (6)	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '64'	(b) (4), (b) (6)	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User entered 'bpm'	System	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '18'	(b) (4), (b) (6)	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User entered 'breaths/min'	System	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '127'	(b) (4), (b) (6)	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User entered 'mmHg'	System	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '75'	(b) (4), (b) (6)	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User entered 'mmHg'	System	06 Oct 2020 15:52:34

US3902020

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 15:52:51

US3902020

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:52:51

US3902020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	30 Sep 2020 18:16:18

US3902020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	Taylor Atkinson (b) (4)	30 Sep 2020 18:16:18

US3902020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

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 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	Taylor Atkinson (b) (4)	30 Sep 2020 18:16:18

US3902020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User entered 'MRNA-1273 OR PLACEBO'	System	30 Sep 2020 18:16:18

US3902020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '30 Sep 2020'	Taylor Atkinson (b) (4)	30 Sep 2020 18:16:18

US3902020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '14:02'	Taylor Atkinson (b) (4)	30 Sep 2020 18:16:18

US3902020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User entered '30 Sep 2020 14:02'	System	30 Sep 2020 18:16:18

US3902020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Left Arm (LEFT ARM)'	Taylor Atkinson (b) (4)	30 Sep 2020 18:16:18

US3902020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User entered 'ONCE'	System	30 Sep 2020 18:16:18

US3902020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User entered 'INTRAMUSCULAR'	System	30 Sep 2020 18:16:18

US3902020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 15:53:16

US3902020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '30 Sep 2020'	(b) (4), (b) (6)	06 Oct 2020 15:53:16

US3902020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '13:28'	(b) (4), (b) (6)	06 Oct 2020 15:53:16

US3902020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User entered '30 Sep 2020 13:28'	System	06 Oct 2020 15:53:16

US3902020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:16:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '30 Sep 2020'	(b) (4), (b) (6)	06 Oct 2020 15:53:37

US3902020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	06 Oct 2020 15:53:37

US3902020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 15:53:37

US3902020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '13:30'	(b) (4), (b) (6)	06 Oct 2020 15:53:37

US3902020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered '30 Sep 2020 13:30'	System	06 Oct 2020 15:53:37

US3902020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	06 Oct 2020 15:53:37

US3902020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 15:53:37

US3902020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '13:30'	(b) (4), (b) (6)	06 Oct 2020 15:53:37

US3902020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered '30 Sep 2020 13:30'	System	06 Oct 2020 15:53:37

US3902020

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 15:53:44

US3902020

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered 'I'	System	06 Oct 2020 15:53:44

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	30 Sep 2020 18:16:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-30T14:46:24', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'c71abeca-eac7-4ac1-a428-fea04c61f823'	System	30 Sep 2020 18:47:48
User entered 'Yes (Y)'	System	30 Sep 2020 18:47:48

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-30T14:47:35', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'c71abeca-eac7-4ac1-a428-fea04c61f823'	System	30 Sep 2020 18:47:48
User entered '98.0'	System	30 Sep 2020 18:47:48

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-30T14:47:42', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'c71abeca-eac7-4ac1-a428-fea04c61f823'	System	30 Sep 2020 18:47:48
User entered 'No (N)'	System	30 Sep 2020 18:47:48

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-30T14:47:45', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'c71abeca-eac7-4ac1-a428-fea04c61f823'	System	30 Sep 2020 18:47:48
User entered '30 Sep 2020 14:47'	System	30 Sep 2020 18:47:48

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '30 Sep 2020 14:22'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '30 Sep 2020 16:52'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	30 Sep 2020 18:16:18
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-01T10:35:56', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '58095fa4-180a-483d-83ae-de0e558fa096'	System	01 Oct 2020 14:36:12
User entered 'Yes (Y)'	System	01 Oct 2020 14:36:12

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-01T10:36:02', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '58095fa4-180a-483d-83ae-de0e558fa096'	System	01 Oct 2020 14:36:12
User entered '97.8'	System	01 Oct 2020 14:36:12

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-01T10:36:06', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '58095fa4-180a-483d-83ae-de0e558fa096'	System	01 Oct 2020 14:36:12
User entered 'No (N)'	System	01 Oct 2020 14:36:12

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-01T10:36:08', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '58095fa4-180a-483d-83ae-de0e558fa096'	System	01 Oct 2020 14:36:12
User entered '01 Oct 2020 10:36'	System	01 Oct 2020 14:36:12

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '30 Sep 2020 17:47'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	30 Sep 2020 18:16:18
User entered 'Day 2'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	30 Sep 2020 18:16:18
User entered 'Day 3'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-02T12:26:31', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'b5a08060-09ca-49d2-9a6f-db83018168a2'	System	02 Oct 2020 16:26:55
User entered 'Yes (Y)'	System	02 Oct 2020 16:26:55

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-02T12:26:44', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'b5a08060-09ca-49d2-9a6f-db83018168a2'	System	02 Oct 2020 16:26:55
User entered '97.6'	System	02 Oct 2020 16:26:55

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-02T12:26:49', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'b5a08060-09ca-49d2-9a6f-db83018168a2'	System	02 Oct 2020 16:26:55
User entered 'No (N)'	System	02 Oct 2020 16:26:55

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-02T12:26:51', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'b5a08060-09ca-49d2-9a6f-db83018168a2'	System	02 Oct 2020 16:26:55
User entered '02 Oct 2020 12:26'	System	02 Oct 2020 16:26:55

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	30 Sep 2020 18:16:18
User entered 'Day 4'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-03T12:28:30', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '464f033a-0dd0-46f0-963e-09c6bfcec4c4'	System	03 Oct 2020 16:29:14
User entered 'Yes (Y)'	System	03 Oct 2020 16:29:14

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-03T12:28:35', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '464f033a-0dd0-46f0-963e-09c6bfcec4c4'	System	03 Oct 2020 16:29:14
User entered '96.9'	System	03 Oct 2020 16:29:14

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-03T12:28:38', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '464f033a-0dd0-46f0-963e-09c6bfcec4c4'	System	03 Oct 2020 16:29:14
User entered 'No (N)'	System	03 Oct 2020 16:29:14

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-03T12:29:12', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '464f033a-0dd0-46f0-963e-09c6bfcec4c4'	System	03 Oct 2020 16:29:14
User entered '03 Oct 2020 12:29'	System	03 Oct 2020 16:29:14

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	30 Sep 2020 18:16:18
User entered 'Day 5'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-04T12:02:18', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'bd6c35c5-a755-4928-b4de-b2d14ff07752'	System	04 Oct 2020 16:02:41
User entered 'Yes (Y)'	System	04 Oct 2020 16:02:41

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-04T12:02:22', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'bd6c35c5-a755-4928-b4de-b2d14ff07752'	System	04 Oct 2020 16:02:41
User entered '96.5'	System	04 Oct 2020 16:02:41

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-04T12:02:25', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'bd6c35c5-a755-4928-b4de-b2d14ff07752'	System	04 Oct 2020 16:02:41
User entered 'No (N)'	System	04 Oct 2020 16:02:41

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-04T12:02:28', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'bd6c35c5-a755-4928-b4de-b2d14ff07752'	System	04 Oct 2020 16:02:41
User entered '04 Oct 2020 12:02'	System	04 Oct 2020 16:02:41

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	30 Sep 2020 18:16:18
User entered 'Day 6'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	30 Sep 2020 18:16:18
User entered 'Day 7'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	30 Sep 2020 18:16:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-30T14:47:53', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'b5fac2a4-0e66-4964-aec4-13c1ec1d5120'	System	30 Sep 2020 18:48:16
User entered 'None (1)'	System	30 Sep 2020 18:48:16

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-30T14:47:57', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'b5fac2a4-0e66-4964-aec4-13c1ec1d5120'	System	30 Sep 2020 18:48:16
User entered 'No (N)'	System	30 Sep 2020 18:48:16

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-30T14:48:00', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'b5fac2a4-0e66-4964-aec4-13c1ec1d5120'	System	30 Sep 2020 18:48:16
User entered 'No (N)'	System	30 Sep 2020 18:48:16

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-30T14:48:05', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'b5fac2a4-0e66-4964-aec4-13c1ec1d5120'	System	30 Sep 2020 18:48:16
User entered 'None (1)'	System	30 Sep 2020 18:48:16

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-30T14:48:14', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'b5fac2a4-0e66-4964-aec4-13c1ec1d5120'	System	30 Sep 2020 18:48:16
User entered '30 Sep 2020 14:48'	System	30 Sep 2020 18:48:16

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '30 Sep 2020 14:22'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '30 Sep 2020 16:52'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	30 Sep 2020 18:16:18
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-01T10:36:17', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '378d9266-06aa-4225-87b5-d991af650577'	System	01 Oct 2020 14:36:43
User entered 'None (1)'	System	01 Oct 2020 14:36:43

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-01T10:36:32', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '378d9266-06aa-4225-87b5-d991af650577'	System	01 Oct 2020 14:36:43
User entered 'No (N)'	System	01 Oct 2020 14:36:43

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-01T10:36:35', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '378d9266-06aa-4225-87b5-d991af650577'	System	01 Oct 2020 14:36:43
User entered 'No (N)'	System	01 Oct 2020 14:36:43

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-01T10:36:38', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '378d9266-06aa-4225-87b5-d991af650577'	System	01 Oct 2020 14:36:43
User entered 'None (1)'	System	01 Oct 2020 14:36:43

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-01T10:36:40', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '378d9266-06aa-4225-87b5-d991af650577'	System	01 Oct 2020 14:36:43
User entered '01 Oct 2020 10:36'	System	01 Oct 2020 14:36:43

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '30 Sep 2020 17:47'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	30 Sep 2020 18:16:18
User entered 'Day 2'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

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)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	30 Sep 2020 18:16:18
User entered 'Day 3'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-02T12:26:56', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '889dd3fb-22ae-438e-ad3e-1eb741b93ca5'	System	02 Oct 2020 16:27:11
User entered 'None (1)'	System	02 Oct 2020 16:27:11

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-02T12:26:59', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '889dd3fb-22ae-438e-ad3e-1eb741b93ca5'	System	02 Oct 2020 16:27:11
User entered 'No (N)'	System	02 Oct 2020 16:27:11

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-02T12:27:02', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '889dd3fb-22ae-438e-ad3e-1eb741b93ca5'	System	02 Oct 2020 16:27:11
User entered 'No (N)'	System	02 Oct 2020 16:27:11

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-02T12:27:04', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '889dd3fb-22ae-438e-ad3e-1eb741b93ca5'	System	02 Oct 2020 16:27:11
User entered 'None (1)'	System	02 Oct 2020 16:27:11

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-02T12:27:08', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '889dd3fb-22ae-438e-ad3e-1eb741b93ca5'	System	02 Oct 2020 16:27:11
User entered '02 Oct 2020 12:27'	System	02 Oct 2020 16:27:11

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	30 Sep 2020 18:16:18
User entered 'Day 4'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-03T12:29:37', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '7dc5fe4a-2eaa-483f-b422-ced02a8f61cf'	System	03 Oct 2020 16:29:55
User entered 'None (1)'	System	03 Oct 2020 16:29:55

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-03T12:29:40', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '7dc5fe4a-2eaa-483f-b422-ced02a8f61cf'	System	03 Oct 2020 16:29:55
User entered 'No (N)'	System	03 Oct 2020 16:29:55

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-03T12:29:42', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '7dc5fe4a-2eaa-483f-b422-ced02a8f61cf'	System	03 Oct 2020 16:29:55
User entered 'No (N)'	System	03 Oct 2020 16:29:55

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-03T12:29:45', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '7dc5fe4a-2eaa-483f-b422-ced02a8f61cf'	System	03 Oct 2020 16:29:55
User entered 'None (1)'	System	03 Oct 2020 16:29:55

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-03T12:29:48', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '7dc5fe4a-2eaa-483f-b422-ced02a8f61cf'	System	03 Oct 2020 16:29:55
User entered '03 Oct 2020 12:29'	System	03 Oct 2020 16:29:55

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	30 Sep 2020 18:16:18
User entered 'Day 5'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-04T12:02:33', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'b666bef4-8ea4-4851-97d6-db2671eba80e'	System	04 Oct 2020 16:02:47
User entered 'None (1)'	System	04 Oct 2020 16:02:47

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-04T12:02:35', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'b666bef4-8ea4-4851-97d6-db2671eba80e'	System	04 Oct 2020 16:02:47
User entered 'No (N)'	System	04 Oct 2020 16:02:47

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-04T12:02:36', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'b666bef4-8ea4-4851-97d6-db2671eba80e'	System	04 Oct 2020 16:02:47
User entered 'No (N)'	System	04 Oct 2020 16:02:47

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-04T12:02:39', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'b666bef4-8ea4-4851-97d6-db2671eba80e'	System	04 Oct 2020 16:02:47
User entered 'None (1)'	System	04 Oct 2020 16:02:47

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-04T12:02:42', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'b666bef4-8ea4-4851-97d6-db2671eba80e'	System	04 Oct 2020 16:02:47
User entered '04 Oct 2020 12:02'	System	04 Oct 2020 16:02:47

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	30 Sep 2020 18:16:18
User entered 'Day 6'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	30 Sep 2020 18:16:18
User entered 'Day 7'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	30 Sep 2020 18:16:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-30T14:48:21', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'c32a87e2-f339-414e-8e4c-62a0fec3d423'	System	30 Sep 2020 18:48:45
User entered 'None (0)'	System	30 Sep 2020 18:48:45

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-30T14:48:23', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'c32a87e2-f339-414e-8e4c-62a0fec3d423'	System	30 Sep 2020 18:48:45
User entered 'None (0)'	System	30 Sep 2020 18:48:45

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-30T14:48:30', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'c32a87e2-f339-414e-8e4c-62a0fec3d423'	System	30 Sep 2020 18:48:45
User entered 'None (0)'	System	30 Sep 2020 18:48:45

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-30T14:48:32', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'c32a87e2-f339-414e-8e4c-62a0fec3d423'	System	30 Sep 2020 18:48:45
User entered 'None (0)'	System	30 Sep 2020 18:48:45

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-30T14:48:35', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'c32a87e2-f339-414e-8e4c-62a0fec3d423'	System	30 Sep 2020 18:48:45
User entered 'None (0)'	System	30 Sep 2020 18:48:45

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-30T14:48:37', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'c32a87e2-f339-414e-8e4c-62a0fec3d423'	System	30 Sep 2020 18:48:45
User entered 'None (0)'	System	30 Sep 2020 18:48:45

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-30T14:48:40', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'c32a87e2-f339-414e-8e4c-62a0fec3d423'	System	30 Sep 2020 18:48:45
User entered 'No (N)'	System	30 Sep 2020 18:48:45

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-09-30T14:48:43', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'c32a87e2-f339-414e-8e4c-62a0fec3d423'	System	30 Sep 2020 18:48:45
User entered '30 Sep 2020 14:48'	System	30 Sep 2020 18:48:45

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '30 Sep 2020 14:22'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '30 Sep 2020 16:52'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	30 Sep 2020 18:16:18
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-01T10:36:45', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '42483240-631b-4535-ac0f-e705d8380d3b'	System	01 Oct 2020 14:37:06
User entered 'None (0)'	System	01 Oct 2020 14:37:06

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-01T10:36:47', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '42483240-631b-4535-ac0f-e705d8380d3b'	System	01 Oct 2020 14:37:06
User entered 'None (0)'	System	01 Oct 2020 14:37:06

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-01T10:36:49', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '42483240-631b-4535-ac0f-e705d8380d3b'	System	01 Oct 2020 14:37:06
User entered 'None (0)'	System	01 Oct 2020 14:37:06

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-01T10:36:51', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '42483240-631b-4535-ac0f-e705d8380d3b'	System	01 Oct 2020 14:37:06
User entered 'None (0)'	System	01 Oct 2020 14:37:06

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-01T10:36:52', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '42483240-631b-4535-ac0f-e705d8380d3b'	System	01 Oct 2020 14:37:06
User entered 'None (0)'	System	01 Oct 2020 14:37:06

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-01T10:36:54', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '42483240-631b-4535-ac0f-e705d8380d3b'	System	01 Oct 2020 14:37:06
User entered 'None (0)'	System	01 Oct 2020 14:37:06

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-01T10:36:56', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '42483240-631b-4535-ac0f-e705d8380d3b'	System	01 Oct 2020 14:37:06
User entered 'No (N)'	System	01 Oct 2020 14:37:06

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-01T10:37:00', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '42483240-631b-4535-ac0f-e705d8380d3b'	System	01 Oct 2020 14:37:06
User entered '01 Oct 2020 10:37'	System	01 Oct 2020 14:37:06

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '30 Sep 2020 17:47'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	30 Sep 2020 18:16:18
User entered 'Day 2'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	30 Sep 2020 18:16:18
User entered 'Day 3'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-02T12:27:13', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '7f73e0c0-2b5f-4c28-8fbd-58d03a454b7a'	System	02 Oct 2020 16:27:42
User entered 'None (0)'	System	02 Oct 2020 16:27:42

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-02T12:27:14', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '7f73e0c0-2b5f-4c28-8fbd-58d03a454b7a'	System	02 Oct 2020 16:27:42
User entered 'None (0)'	System	02 Oct 2020 16:27:42

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-02T12:27:16', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '7f73e0c0-2b5f-4c28-8fbd-58d03a454b7a'	System	02 Oct 2020 16:27:42
User entered 'None (0)'	System	02 Oct 2020 16:27:42

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-02T12:27:18', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '7f73e0c0-2b5f-4c28-8fbd-58d03a454b7a'	System	02 Oct 2020 16:27:42
User entered 'None (0)'	System	02 Oct 2020 16:27:42

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-02T12:27:19', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '7f73e0c0-2b5f-4c28-8fbd-58d03a454b7a'	System	02 Oct 2020 16:27:42
User entered 'None (0)'	System	02 Oct 2020 16:27:42

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-02T12:27:21', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '7f73e0c0-2b5f-4c28-8fbd-58d03a454b7a'	System	02 Oct 2020 16:27:42
User entered 'None (0)'	System	02 Oct 2020 16:27:42

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-02T12:27:23', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '7f73e0c0-2b5f-4c28-8fbd-58d03a454b7a'	System	02 Oct 2020 16:27:42
User entered 'No (N)'	System	02 Oct 2020 16:27:42

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-02T12:27:25', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '7f73e0c0-2b5f-4c28-8fbd-58d03a454b7a'	System	02 Oct 2020 16:27:42
User entered '02 Oct 2020 12:27'	System	02 Oct 2020 16:27:42

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	30 Sep 2020 18:16:18
User entered 'Day 4'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-03T12:30:19', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'bcc9967d-fe3e-4ad1-a1bf-b284788dbea0'	System	03 Oct 2020 16:30:37
User entered 'None (0)'	System	03 Oct 2020 16:30:37

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-03T12:30:21', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'bcc9967d-fe3e-4ad1-a1bf-b284788dbea0'	System	03 Oct 2020 16:30:37
User entered 'None (0)'	System	03 Oct 2020 16:30:37

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-03T12:30:22', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'bcc9967d-fe3e-4ad1-a1bf-b284788dbea0'	System	03 Oct 2020 16:30:37
User entered 'None (0)'	System	03 Oct 2020 16:30:37

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-03T12:30:24', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'bcc9967d-fe3e-4ad1-a1bf-b284788dbea0'	System	03 Oct 2020 16:30:37
User entered 'None (0)'	System	03 Oct 2020 16:30:37

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-03T12:30:25', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'bcc9967d-fe3e-4ad1-a1bf-b284788dbea0'	System	03 Oct 2020 16:30:37
User entered 'None (0)'	System	03 Oct 2020 16:30:37

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-03T12:30:27', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'bcc9967d-fe3e-4ad1-a1bf-b284788dbea0'	System	03 Oct 2020 16:30:37
User entered 'None (0)'	System	03 Oct 2020 16:30:37

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-03T12:30:30', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'bcc9967d-fe3e-4ad1-a1bf-b284788dbea0'	System	03 Oct 2020 16:30:37
User entered 'No (N)'	System	03 Oct 2020 16:30:37

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-03T12:30:32', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'bcc9967d-fe3e-4ad1-a1bf-b284788dbea0'	System	03 Oct 2020 16:30:37
User entered '03 Oct 2020 12:30'	System	03 Oct 2020 16:30:37

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	30 Sep 2020 18:16:18
User entered 'Day 5'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-04T12:02:47', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '6a770eeb-9f51-41cb-bc14-0b30a38fc396'	System	04 Oct 2020 16:03:14
User entered 'None (0)'	System	04 Oct 2020 16:03:14

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-04T12:02:48', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '6a770eeb-9f51-41cb-bc14-0b30a38fc396'	System	04 Oct 2020 16:03:14
User entered 'None (0)'	System	04 Oct 2020 16:03:14

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-04T12:02:50', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '6a770eeb-9f51-41cb-bc14-0b30a38fc396'	System	04 Oct 2020 16:03:14
User entered 'None (0)'	System	04 Oct 2020 16:03:14

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-04T12:02:51', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '6a770eeb-9f51-41cb-bc14-0b30a38fc396'	System	04 Oct 2020 16:03:14
User entered 'None (0)'	System	04 Oct 2020 16:03:14

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-04T12:02:53', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '6a770eeb-9f51-41cb-bc14-0b30a38fc396'	System	04 Oct 2020 16:03:14
User entered 'None (0)'	System	04 Oct 2020 16:03:14

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-04T12:02:56', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '6a770eeb-9f51-41cb-bc14-0b30a38fc396'	System	04 Oct 2020 16:03:14
User entered 'None (0)'	System	04 Oct 2020 16:03:14

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-04T12:02:59', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '6a770eeb-9f51-41cb-bc14-0b30a38fc396'	System	04 Oct 2020 16:03:14
User entered 'No (N)'	System	04 Oct 2020 16:03:14

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c28426e4b08a2750)', Time: '2020-10-04T12:03:10', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '6a770eeb-9f51-41cb-bc14-0b30a38fc396'	System	04 Oct 2020 16:03:14
User entered '04 Oct 2020 12:03'	System	04 Oct 2020 16:03:14

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	30 Sep 2020 18:16:18
User entered 'Day 6'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
Data entry locked.	System	30 Sep 2020 18:16:18
User entered 'Day 7'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

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 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 18:16:18

US3902020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:13
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 18:16:18

US3902020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 14:50:25

US3902020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 14:50:25

US3902020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Oct 2020 14:50:25

US3902020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 14:50:25

US3902020

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 14:50:32

US3902020

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered 'I'	System	09 Oct 2020 14:50:32

US3902020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	Katrina Carlson (b) (4)	14 Oct 2020 23:36:03

US3902020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '14 Oct 2020'	Katrina Carlson (b) (4)	14 Oct 2020 23:36:03

US3902020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Contact Made (CONTACT MADE)'	Katrina Carlson (b) (4)	14 Oct 2020 23:36:03

US3902020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	Katrina Carlson (b) (4)	14 Oct 2020 23:36:03

US3902020

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	Katrina Carlson (b) (4)	14 Oct 2020 23:36:07

US3902020

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered 'I'	System	14 Oct 2020 23:36:07

US3902020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 28OCT2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 13:38:28
Query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 28OCT2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' answered with 'site confirms samples were shipped, and received 12nov2020' (Site from DM).	Bram Swarr (b) (4)	12 Dec 2020 16:34:45
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 28OCT2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 00:48:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 18:10:59

US3902020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '23 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 18:10:59

US3902020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Nov 2020 18:10:59

US3902020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 18:10:59

US3902020

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 18:11:03

US3902020

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered 'I'	System	06 Nov 2020 18:11:03

US3902020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:03:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Nov 2020 19:21:21

US3902020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:03:14
User entered '28 Oct 2020'	(b) (4), (b) (6)	24 Nov 2020 19:21:21

US3902020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[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 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:03:14
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Nov 2020 19:21:21

US3902020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User entered 'VISIT3'	System	24 Nov 2020 19:21:21

US3902020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:03:14
User entered 'No (N)'	(b) (4), (b) (6)	24 Nov 2020 19:21:34

US3902020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:03:14
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:21:34

US3902020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:03:14
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:21:34

US3902020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User entered empty.	System	24 Nov 2020 19:21:34

US3902020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:03:14
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:21:34

US3902020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:03:14
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:21:34

US3902020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:03:14
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:21:34

US3902020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:03:14
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:21:34

US3902020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User entered empty.	System	24 Nov 2020 19:21:34

US3902020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:03:14
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:21:34

US3902020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User entered empty.	System	24 Nov 2020 19:21:34

US3902020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:03:14
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:21:34

US3902020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User entered empty.	System	24 Nov 2020 19:21:34

US3902020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:03:14
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:21:34

US3902020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User entered empty.	System	24 Nov 2020 19:21:34

US3902020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04

US3902020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04

US3902020

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:03:14
User entered 'No (N)'	(b) (4), (b) (6)	24 Nov 2020 19:21:39

US3902020

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:03:14
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:21:39

US3902020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:03:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Nov 2020 19:21:56

US3902020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:03:14
User entered '28 Oct 2020'	(b) (4), (b) (6)	24 Nov 2020 19:21:56

US3902020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:03:14
User entered '15:22'	(b) (4), (b) (6)	24 Nov 2020 19:21:56

US3902020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User entered '28 Oct 2020 15:22'	System	24 Nov 2020 19:21:56

US3902020

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Nov 2020 19:22:02

US3902020

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:04
User entered 'I'	System	24 Nov 2020 19:22:02

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26
Data entry locked.	System	02 Sep 2020 22:25:24
User entered 'Day 64'	System	02 Sep 2020 22:25:24

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Have you been exposed to someone with 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 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Please 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 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Please 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 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Please 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 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26
Data entry locked.	System	02 Sep 2020 22:25:24
User entered '02 Nov 2020 00:01'	System	02 Sep 2020 22:25:24

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26
Data entry locked.	System	02 Sep 2020 22:25:24
User entered '06 Nov 2020 23:59'	System	02 Sep 2020 22:25:24

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26
Data entry locked.	System	02 Sep 2020 22:25:24
User entered 'Day 71'	System	02 Sep 2020 22:25:24

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Have you been exposed to someone with 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 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Please 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 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Please 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 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Please 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 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26
Data entry locked.	System	02 Sep 2020 22:25:24
User entered '09 Nov 2020 00:01'	System	02 Sep 2020 22:25:24

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26
Data entry locked.	System	02 Sep 2020 22:25:24
User entered '13 Nov 2020 23:59'	System	02 Sep 2020 22:25:24

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26
Data entry locked.	System	02 Sep 2020 22:25:24
User entered 'Day 78'	System	02 Sep 2020 22:25:24

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Have you been exposed to someone with 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 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Please 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 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Please 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 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Please 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 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

US3902020

Folder: Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26

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Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26
Data entry locked.	System	02 Sep 2020 22:25:24
User entered '16 Nov 2020 00:01'	System	02 Sep 2020 22:25:24

US3902020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:26
Data entry locked.	System	02 Sep 2020 22:25:24
User entered '20 Nov 2020 23:59'	System	02 Sep 2020 22:25:24

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (980f989a5b080896)', Time: '2021-01-04T20:41:36', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '4af11b8d-1a9e-4d72-9c2a-1064c2917e2c'	System	05 Jan 2021 01:41:53
User entered 'No (N)'	System	05 Jan 2021 01:41:53

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Have you been exposed to someone with 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 (980f989a5b080896)', Time: '2021-01-04T20:41:43', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '4af11b8d-1a9e-4d72-9c2a-1064c2917e2c'	System	05 Jan 2021 01:41:53
User entered 'No (N)'	System	05 Jan 2021 01:41:53

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (980f989a5b080896)', Time: '2021-01-04T20:41:51', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '4af11b8d-1a9e-4d72-9c2a-1064c2917e2c'	System	05 Jan 2021 01:41:53
User entered '04 Jan 2021 20:41:51'	System	05 Jan 2021 01:41:53

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (980f989a5b080896)', Time: '2021-03-23T09:58:18-04:00', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '63d80e2f-4436-4f34-9fb8-cf8135984a30'	System	23 Mar 2021 13:58:35
User entered 'No (N)'	System	23 Mar 2021 13:58:35

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Have you been exposed to someone with 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 (980f989a5b080896)', Time: '2021-03-23T09:58:22-04:00', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '63d80e2f-4436-4f34-9fb8-cf8135984a30'	System	23 Mar 2021 13:58:35
User entered 'No (N)'	System	23 Mar 2021 13:58:35

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (980f989a5b080896)', Time: '2021-03-23T09:58:26-04:00', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '63d80e2f-4436-4f34-9fb8-cf8135984a30'	System	23 Mar 2021 13:58:35
User entered '23 Mar 2021 09:58:26'	System	23 Mar 2021 13:58:35

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (980f989a5b080896)', Time: '2021-04-06T12:59:08-04:00', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'd6b0a281-7719-4dad-8be7-c15bbb552446'	System	06 Apr 2021 16:59:21
User entered 'No (N)'	System	06 Apr 2021 16:59:21

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Have you been exposed to someone with 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 (980f989a5b080896)', Time: '2021-04-06T12:59:12-04:00', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'd6b0a281-7719-4dad-8be7-c15bbb552446'	System	06 Apr 2021 16:59:21
User entered 'No (N)'	System	06 Apr 2021 16:59:21

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (980f989a5b080896)', Time: '2021-04-06T12:59:17-04:00', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'd6b0a281-7719-4dad-8be7-c15bbb552446'	System	06 Apr 2021 16:59:21
User entered '06 Apr 2021 12:59:17'	System	06 Apr 2021 16:59:21

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (980f989a5b080896)', Time: '2021-04-12T17:41:39-04:00', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '455b64cc-7be4-4b2f-85b4-a66252a9e31d'	System	12 Apr 2021 21:41:55
User entered 'No (N)'	System	12 Apr 2021 21:41:55

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Have you been exposed to someone with 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 (980f989a5b080896)', Time: '2021-04-12T17:41:48-04:00', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '455b64cc-7be4-4b2f-85b4-a66252a9e31d' User entered 'No (N)'	System	12 Apr 2021 21:41:55
	System	12 Apr 2021 21:41:55

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (980f989a5b080896)', Time: '2021-04-12T17:41:51-04:00', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '455b64cc-7be4-4b2f-85b4-a66252a9e31d'	System	12 Apr 2021 21:41:55
User entered '12 Apr 2021 17:41:51'	System	12 Apr 2021 21:41:55

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (980f989a5b080896)', Time: '2021-04-17T22:03:28-04:00', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '29b03575-00e2-45c1-8315-5195b1640b3b'	System	18 Apr 2021 02:05:15
User entered 'No (N)'	System	18 Apr 2021 02:05:15

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Have you been exposed to someone with 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 (980f989a5b080896)', Time: '2021-04-17T22:03:35-04:00', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '29b03575-00e2-45c1-8315-5195b1640b3b'	System	18 Apr 2021 02:05:15
User entered 'No (N)'	System	18 Apr 2021 02:05:15

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (980f989a5b080896)', Time: '2021-04-17T22:03:38-04:00', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '29b03575-00e2-45c1-8315-5195b1640b3b'	System	18 Apr 2021 02:05:15
User entered '17 Apr 2021 22:03:38'	System	18 Apr 2021 02:05:15

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (980f989a5b080896)', Time: '2021-04-25T17:16:15-04:00', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '0a8f0f45-785a-4679-baa2-be09361d61bb' User entered 'No (N)'	System	25 Apr 2021 21:16:28
	System	25 Apr 2021 21:16:28

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Have you been exposed to someone with 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 (980f989a5b080896)', Time: '2021-04-25T17:16:19-04:00', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '0a8f0f45-785a-4679-baa2-be09361d61bb'	System	25 Apr 2021 21:16:28
User entered 'No (N)'	System	25 Apr 2021 21:16:28

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (980f989a5b080896)', Time: '2021-04-25T17:16:24-04:00', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '0a8f0f45-785a-4679-baa2-be09361d61bb' User entered '25 Apr 2021 17:16:24'	System	25 Apr 2021 21:16:28
	System	25 Apr 2021 21:16:28

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (980f989a5b080896)', Time: '2021-05-02T14:48:59-04:00', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '3984e925-8dcb-48ca-9232-1264c9d8dc5e'	System	02 May 2021 18:50:17
User entered 'No (N)'	System	02 May 2021 18:50:17

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Have you been exposed to someone with 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 (980f989a5b080896)', Time: '2021-05-02T14:49:53-04:00', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '3984e925-8dcb-48ca-9232-1264c9d8dc5e'	System	02 May 2021 18:50:17
User entered 'Yes (Y)'	System	02 May 2021 18:50:17

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Please 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 (980f989a5b080896)', Time: '2021-05-02T14:49:57-04:00', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '3984e925-8dcb-48ca-9232-1264c9d8dc5e'	System	02 May 2021 18:50:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 May 2021 18:50:17

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (980f989a5b080896)', Time: '2021-05-02T14:50:03-04:00', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: '3984e925-8dc9-48ca-9232-1264c9d8dc5e'	System	02 May 2021 18:50:17
User entered '02 May 2021 14:50:03'	System	02 May 2021 18:50:17

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 02:58:26

US3902020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:26
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 02:58:26

US3902020

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:16:35

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 06:28:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (980f989a5b080896)', Time: '2021-03-10T10:03:13-05:00', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'ddd40e0e-db55-484d-a789-53c51b5832b2'	System	10 Mar 2021 15:03:24
User entered 'No (N)'	System	10 Mar 2021 15:03:24

US3902020

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:16:35

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (980f989a5b080896)', Time: '2021-03-10T10:03:18-05:00', User OID: 'PatientReportedOutcome (US3902020)', ODM File OID: 'ddd40e0e-db55-484d-a789-53c51b5832b2'	System	10 Mar 2021 15:03:24
User entered '10 Mar 2021 10:03:18'	System	10 Mar 2021 15:03:24

US3902020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Dec 2020 19:40:24

US3902020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '25 Nov 2020'	(b) (4), (b) (6)	05 Dec 2020 19:40:24

US3902020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Dec 2020 19:40:24

US3902020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	(b) (4), (b) (6)	05 Dec 2020 19:40:24

US3902020

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Dec 2020 19:40:29

US3902020

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 05:24:03
User entered 'I'	System	05 Dec 2020 19:40:29

US3902020

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:51:02
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	31 Dec 2020 15:13:27

US3902020

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:51:02
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '31 Dec 2020'	Taylor Atkinson (b) (4)	31 Dec 2020 15:13:27

US3902020

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:51:02
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Contact Made (CONTACT MADE)'	Taylor Atkinson (b) (4)	31 Dec 2020 15:13:27

US3902020

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:51:02
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	Taylor Atkinson (b) (4)	31 Dec 2020 15:13:27

US3902020

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:51:02
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	31 Dec 2020 15:13:55

US3902020

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:51:02
User entered 'I'	System	31 Dec 2020 15:13:55

US3902020

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:51:02
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	Bram Swarr (b) (4)	29 Jan 2021 21:34:48

US3902020

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:51:02
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered '28 Jan 2021'	Bram Swarr (b) (4)	29 Jan 2021 21:34:48

US3902020

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:51:02
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Contact Made (CONTACT MADE)'	Bram Swarr (b) (4)	29 Jan 2021 21:34:48

US3902020

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:51:02
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered empty.	Bram Swarr (b) (4)	29 Jan 2021 21:34:48

US3902020

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:51:02
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'Yes (Y)'	Bram Swarr (b) (4)	29 Jan 2021 21:35:01

US3902020

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:51:02
User entered 'I'	System	29 Jan 2021 21:35:01

US3902020

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:07:28
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:11
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	05 Mar 2021 16:42:46

US3902020

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:07:28
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:11
User entered '24 Feb 2021'	Taylor Atkinson (b) (4)	05 Mar 2021 16:42:46

US3902020

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:07:28
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:11
User entered 'Contact Made (CONTACT MADE)'	Taylor Atkinson (b) (4)	05 Mar 2021 16:42:46

US3902020

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:07:28
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:11
User entered empty.	Taylor Atkinson (b) (4)	05 Mar 2021 16:42:46

US3902020

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:07:28
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	05 Mar 2021 16:42:51

US3902020

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:07:28
User entered 'I'	System	05 Mar 2021 16:42:51

US3902020

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

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	15 Mar 2021 12:56:21
	(b) (4)	

US3902020

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

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
User entered '10 Mar 2021'	Taylor Atkinson (b) (4)	15 Mar 2021 12:56:21
	(b) (4)	

US3902020

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

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[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 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
User entered 'Clinic (Clinic)'	Taylor Atkinson (b) (4)	15 Mar 2021 12:56:21
	(b) (4)	

US3902020

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

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User entered 'UNBLND_DECIDE'	System	15 Mar 2021 12:56:21

US3902020

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
User entered '10 Mar 2021'	Taylor Atkinson (b) (4)	15 Mar 2021 12:56:46
	(b) (4)	

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

[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 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
User entered '0'	Taylor Atkinson (b) (4)	15 Mar 2021 12:56:46
	(b) (4)	

US3902020

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	15 Mar 2021 12:56:46
	(b) (4)	

US3902020

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
User entered 'Amendment 6 or later (Amendment 6 or later)'	Taylor Atkinson (b) (4)	15 Mar 2021 12:56:46

US3902020

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
User entered '10 Mar 2021'	Taylor Atkinson (b) (4)	15 Mar 2021 12:56:46
	(b) (4)	

US3902020

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
User entered 'mRNA-1273 (mRNA-1273)'	Taylor Atkinson (b) (4)	15 Mar 2021 12:56:46
	(b) (4)	

US3902020

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
User entered 'mRNA-1273 (mRNA-1273)'	Taylor Atkinson (b) (4)	15 Mar 2021 12:56:46
	(b) (4)	

US3902020

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
User entered 'mRNA-1273 (mRNA-1273)'	Taylor Atkinson (b) (4)	15 Mar 2021 12:56:46
	(b) (4)	

US3902020

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
User entered 'No (N)'	Taylor Atkinson (b) (4)	15 Mar 2021 12:56:46
	(b) (4)	

US3902020

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User entered empty.	System	15 Mar 2021 12:56:46

US3902020

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User entered empty.	System	15 Mar 2021 12:56:46

US3902020

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	15 Mar 2021 12:57:13
	(b) (4)	

US3902020

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
User entered '10 Mar 2021'	Taylor Atkinson (b) (4)	15 Mar 2021 12:57:13
	(b) (4)	

US3902020

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
User entered '11:02'	Taylor Atkinson (b) (4)	15 Mar 2021 12:57:13
	(b) (4)	

US3902020

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User entered '10 Mar 2021 11:02'	System	15 Mar 2021 12:57:13

US3902020

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	15 Mar 2021 12:57:35
	(b) (4)	

US3902020

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:16:35

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
User entered '10 Mar 2021'	Taylor Atkinson (b) (4)	15 Mar 2021 12:57:35
	(b) (4)	

US3902020

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:16:35

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
User entered '11:04'	Taylor Atkinson (b) (4)	15 Mar 2021 12:57:35
	(b) (4)	

US3902020

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:16:35

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:29:19
User entered '10 Mar 2021 11:04'	System	15 Mar 2021 12:57:35

US3902020

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:16:35

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:17:32
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:38:02
User entered 'Yes (Y)'	Katrina Carlson (b) (4)	25 Feb 2021 21:44:33

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 15:27:36
User entered 'USA-US210-2021-mRNA-1273-P301000001'	System	26 Feb 2021 15:27:33
User entered 'New'	(b) (4), (b) (6)	26 Feb 2021 15:27:33

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 22:03:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 22:03:01
Data point term sent to Coder	System	25 Feb 2021 22:02:30
User entered 'myocardial infarction'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User entered 'Yes (Y)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User entered 'No (N)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User entered 'No (N)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User entered '15 Feb 2021'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User entered empty.	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User entered 'No (N)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User entered '16 Feb 2021'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User entered empty.	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User entered 'Grade 3/Severe (Grade 3/Severe)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	25 Feb 2021 22:03:00
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	25 Feb 2021 22:02:04
User entered 'Yes (Y)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User entered '0'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User entered '0'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		25 Feb 2021 22:03:00
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		25 Feb 2021 22:03:00
User entered '1' reason for change: Data Entry Error	Katrina Carlson (b) (4)	25 Feb 2021 22:03:00
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) System	25 Feb 2021 22:02:04
User entered '0'	Katrina Carlson (b) (4)	25 Feb 2021 22:02:04
	(b) (4)	

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User entered '15 Feb 2021'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User entered '18 Feb 2021'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User entered 'No (N)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User entered empty.	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User entered '0'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User entered '0'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User entered '0'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User entered 'Not Related (NOT RELATED)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User entered 'Not Related (NOT RELATED)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User entered 'Not Applicable (NOT APPLICABLE)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User entered '0'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User opened query 'PER CDM: Re-Query: As per previous response it was reported as 'pending medical records'. However, request you please keep this query open until site get records and data recorded as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 05:54:28
User closed query 'Per CDM: Concomitant Medication is checked Yes, however, there is no corresponding medication recorded on the Prior and Concomitant Medications form with an Indication of MYOCARDIAL INFARCTION. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 05:54:28
Query 'Per CDM: Concomitant Medication is checked Yes, however, there is no corresponding medication recorded on the Prior and Concomitant Medications form with an Indication of MYOCARDIAL INFARCTION. Please clarify and update as appropriate.' answered with 'Subject stated they took meds due to SAE, but they did not remember the med. Site is pending medical records to complete this section' (Site from DM).	Taylor Atkinson (b) (4) (b) (4)	20 Apr 2021 17:03:16
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so. ' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 12:54:22
User opened query 'Per CDM: Concomitant Medication is checked Yes, however, there is no corresponding medication recorded on the Prior and Concomitant Medications form with an Indication of MYOCARDIAL INFARCTION. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 11:53:31
User entered 'I'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User entered '0'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User entered empty.	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:54:24
User closed query 'Please fix spelling to a cardiac stent "placed" and told due to "intubation"?' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 15:07:48
User opened query 'PER DM CLR: Re-Query: As per previous response it was reported as 'pending medical records'. However, request you please keep this query open until site get records and data recorded as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 05:55:31
User closed query 'Per DM CLR: Narrative indicates that subject had "CARDIAC STENT PACED ON 16FEB2021." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 05:55:31
Query 'Please fix spelling to a cardiac stent "placed" and told due to "intubation"?' answered with 'corrected' (Site from CRA).	Taylor Atkinson (b) (4)	20 Apr 2021 17:05:45
User entered 'DURING DAY 149 SAFETY CALL, SUBJECT STATED HE WAS ADMITTED TO PARRISH MEDICAL CENTER ON 2/15/2021, DIAGNOSED AS HAVING A MYOCARDIAL INFARCTION AND A CARDIAC STENT PLACED ON 16FEB2021. SUFFERED A LOWER LUNG INFECTION WHICH SUBJECT WAS TOLD DUE TO INTUBATION. DISCHARGED ON 02/18/2021 WITH MEDICATION FOR HYPERLIPIDEMIA, HYPERTENSION, AND LUNG INFECTION.'	Taylor Atkinson (b) (4)	20 Apr 2021 17:05:10
reason for change: Data Entry Error		
Query 'Per DM CLR: Narrative indicates that subject had "CARDIAC STENT PACED ON 16FEB2021." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'Site is pending medical records to add this to appropriate other CRFs' (Site from DM).	Taylor Atkinson (b) (4)	20 Apr 2021 17:04:23
User opened query 'Please fix spelling to a cardiac stent "placed" and told due to "intubation"?' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:10:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Narrative](#)

Audit	User	Time (GMT)
Query 'SC149 conducted on 28Jan2021. Should this be SC179 conducted on 25Feb2021? Please update EDC accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:09:50
Query 'please review queries below and respond waiting for medical records. Please fix spelling to a cardiac stent "placed" and told due to "intubation"?' canceled (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:09:45
User opened query 'Per DM CLR: Narrative indicates that subject had "CARDIAC STENT PACED ON 16FEB2021." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 06:47:49
User opened query 'SC149 conducted on 28Jan2021. Should this be SC179 conducted on 25Feb2021? Please update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 16:37:17
User opened query 'please review queries below and respond waiting for medical records. Please fix spelling to a cardiac stent "placed" and told due to "intubation"?' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:30:52
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)	05 Mar 2021 12:53:31
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)	05 Mar 2021 12:53:16
User entered 'During Day 149 safety call, subject stated he was admitted to parrish medical center on 2/15/2021, diagnosed as having a myocardial infarction and a cardiac stent paced on 16Feb2021. Suffered a lower lung infection which subject was told due to incubation. Discharged on 02/18/2021 with medication for hyperlipidemia, hypertension, and lung infection.'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:02:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Feb 2021 22:02:04

US3902020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 22:09:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 22:09:01
Data point term sent to Coder	System	25 Feb 2021 22:08:37
User entered 'hyperlipidemia'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:07:57

US3902020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User entered 'Yes (Y)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:07:57

US3902020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User entered 'No (N)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:07:57

US3902020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User entered 'No (N)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:07:57

US3902020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User entered '15 Feb 2021'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:07:57

US3902020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User entered empty.	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:07:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 22:07:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User entered 'Yes (Y)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:07:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User entered empty.	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:07:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User entered empty.	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:07:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 22:07:57

US3902020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User entered 'Grade 1/Mild (Grade 1/Mild)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:07:57

US3902020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User entered 'No (N)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:07:57

US3902020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User entered '0'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:07:57

US3902020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User entered '0'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:07:57

US3902020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User entered '0'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:07:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User entered empty.	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:07:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User entered empty.	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:07:57

US3902020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User entered empty.	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:07:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User entered empty.	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:07:57

US3902020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User entered '0'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:07:57

US3902020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User entered '0'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:07:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User entered '0'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:07:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 22:08:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 22:08:42
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Katrina Carlson (b) (4)	25 Feb 2021 22:08:42
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 22:07:57
User entered empty.	Katrina Carlson (b) (4)	25 Feb 2021 22:07:57

US3902020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 22:08:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 22:08:42
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Katrina Carlson (b) (4)	25 Feb 2021 22:08:42
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 22:07:57
User entered empty.	Katrina Carlson (b) (4)	25 Feb 2021 22:07:57

US3902020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 22:08:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 22:08:42
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Katrina Carlson (b) (4)	25 Feb 2021 22:08:42
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 22:07:57
User entered empty.	Katrina Carlson (b) (4)	25 Feb 2021 22:07:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	25 Feb 2021 22:08:42
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	25 Feb 2021 22:07:57
User entered '0'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:07:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User entered '1' reason for change: Data Entry Error	Katrina Carlson (b) (4)	25 Feb 2021 22:08:42
User entered '0'	Katrina Carlson (b) (4)	25 Feb 2021 22:07:57

US3902020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User entered '0'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:07:57

US3902020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 22:08:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 22:08:42
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:08:42
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 22:07:57
User entered empty.	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:07:57

US3902020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User entered empty.	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:07:57

US3902020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:54
User entered empty.	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:07:57

US3902020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Feb 2021 22:07:57

US3902020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Feb 2021 22:07:57

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
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) (b) (4)	25 Feb 2021 22:12:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 22:12:01
Data point term sent to Coder	System	25 Feb 2021 22:11:41
User entered 'hypertension'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered 'Yes (Y)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered 'No (N)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered 'No (N)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered '16 Feb 2021'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered empty.	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered 'Yes (Y)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered empty.	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered empty.	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered 'Grade 1/Mild (Grade 1/Mild)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered 'No (N)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered '0'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered '0'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered '0'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered empty.	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered empty.	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered empty.	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered empty.	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered '0'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered '0'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered '0'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered 'Not Related (NOT RELATED)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered 'Not Related (NOT RELATED)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered 'Not Applicable (NOT APPLICABLE)'	Katrina Carlson (b) (4)	25 Feb 2021 22:11:11
	(b) (4)	

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered '0'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered 'I'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered '0'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered empty.	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:13:58
User entered empty.	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Feb 2021 22:11:11

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User closed query 'Per MM: Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 08:25:01
Query 'Per MM: Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'Per subject, they were assessed in hospital. Pending medical record results' (Site from DM).	Taylor Atkinson (b) (4) (b) (4)	09 Apr 2021 20:30:07
User opened query 'Per MM: Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 09:35:04
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Lung infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 12:07:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 12:07:44
Data point term sent to Coder	System	25 Feb 2021 22:49:40
User entered 'infection lower lobes of lungs'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:49:22

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered 'Yes (Y)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:49:22

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered 'No (N)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:49:22

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered 'No (N)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:49:22

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered '16 Feb 2021'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:49:22

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered empty.	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:49:22

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered empty.	System	25 Feb 2021 22:49:22

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered 'No (N)'	Katrina Carlson (b) (4)	25 Feb 2021 22:49:22
	(b) (4)	

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered '24 Feb 2021'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:49:22

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered empty.	Katrina Carlson (b) (4)	25 Feb 2021 22:49:22
	(b) (4)	

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered empty.	System	25 Feb 2021 22:49:22

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Katrina Carlson (b) (4)	25 Feb 2021 22:49:22
	(b) (4)	

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered 'No (N)'	Katrina Carlson (b) (4)	25 Feb 2021 22:49:22
	(b) (4)	

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered '0'	Katrina Carlson (b) (4)	25 Feb 2021 22:49:22
	(b) (4)	

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered '0'	Katrina Carlson (b) (4)	25 Feb 2021 22:49:22
	(b) (4)	

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered '0'	Katrina Carlson (b) (4)	25 Feb 2021 22:49:22
	(b) (4)	

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered empty.	Katrina Carlson (b) (4)	25 Feb 2021 22:49:22
	(b) (4)	

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered empty.	Katrina Carlson (b) (4)	25 Feb 2021 22:49:22
	(b) (4)	

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered empty.	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:49:22

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered empty.	Katrina Carlson (b) (4)	25 Feb 2021 22:49:22
	(b) (4)	

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered '0'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:49:22

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered '0'	Katrina Carlson (b) (4)	25 Feb 2021 22:49:22
	(b) (4)	

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered '0'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:49:22

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered 'Not Related (NOT RELATED)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:49:22

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered 'Not Related (NOT RELATED)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:49:22

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered 'Not Applicable (NOT APPLICABLE)'	Katrina Carlson (b) (4)	25 Feb 2021 22:49:22
	(b) (4)	

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered '0'	Katrina Carlson (b) (4)	25 Feb 2021 22:49:22
	(b) (4)	

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered '1'	Katrina Carlson (b) (4)	25 Feb 2021 22:49:22

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered '0'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:49:22

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:49:22

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[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 16:09:01
User entered empty.	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:49:22

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered empty.	Katrina Carlson (b) (4) (b) (4)	25 Feb 2021 22:49:22

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered '0'	System	25 Feb 2021 22:49:22

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered 'I'	System	25 Feb 2021 22:49:22

US3902020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:17:32
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
Signature has been broken.	Katrina Carlson (b) (4)	25 Feb 2021 22:13:40
User entered 'Yes (Y)' reason for change: New Information	Katrina Carlson (b) (4)	25 Feb 2021 22:13:40
User signature succeeded.	Murray Kimmel (b) (4)	19 Feb 2021 22:02:52
User entered 'No (N)'	Bram Swarr (b) (4)	04 Sep 2020 15:08:01

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
	(b) (4), (b) (6)	01 Mar 2021 19:37:31
DataPoint Verified.	Coder Import (b) (4)	25 Feb 2021 22:16:02
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.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 22:16:02
Data point term sent to Coder User entered 'atorvastatin'	System Katrina Carlson (b) (4)	25 Feb 2021 22:15:55 25 Feb 2021 22:15:15

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'No (N)'	Katrina Carlson (b) (4)	25 Feb 2021 22:15:15
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'hyperlipedemia'	Katrina Carlson (b) (4)	25 Feb 2021 22:15:15
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered '40'	Katrina Carlson (b) (4)	25 Feb 2021 22:15:15
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'mg (mg)'	Katrina Carlson (b) (4)	25 Feb 2021 22:15:15
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered empty.	Katrina Carlson (b) (4)	25 Feb 2021 22:15:15
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'once daily (QD)'	Katrina Carlson (b) (4)	25 Feb 2021 22:15:15
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered empty.	Katrina Carlson (b) (4)	25 Feb 2021 22:15:15
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'Oral (ORAL)'	Katrina Carlson (b) (4)	25 Feb 2021 22:15:15
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered empty.	Katrina Carlson (b) (4)	25 Feb 2021 22:15:15
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered '19 Feb 2021'	Katrina Carlson (b) (4)	25 Feb 2021 22:15:15
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered '0'	Katrina Carlson (b) (4)	25 Feb 2021 22:15:15
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'Yes (Y)'	Katrina Carlson (b) (4)	25 Feb 2021 22:15:15
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered empty.	Katrina Carlson (b) (4)	25 Feb 2021 22:15:15
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'No (N)'	Katrina Carlson (b) (4)	25 Feb 2021 22:15:15
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 22:15:15

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 22:15:15

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Feb 2021 22:15:15

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
	(b) (4), (b) (6)	01 Mar 2021 19:37:31
DataPoint Verified.	Coder Import (b) (4)	25 Feb 2021 22:19:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 22:19:01
Data point term sent to Coder User entered 'lisinopril'	System Katrina Carlson (b) (4)	25 Feb 2021 22:17:57 25 Feb 2021 22:17:18

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'No (N)'	Katrina Carlson (b) (4)	25 Feb 2021 22:17:18
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'hypertension'	Katrina Carlson (b) (4)	25 Feb 2021 22:17:18
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered '5'	Katrina Carlson (b) (4)	25 Feb 2021 22:17:18
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'mg (mg)'	Katrina Carlson (b) (4)	25 Feb 2021 22:17:18
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered empty.	Katrina Carlson (b) (4)	25 Feb 2021 22:17:18
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'once daily (QD)'	Katrina Carlson (b) (4)	25 Feb 2021 22:17:18
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered empty.	Katrina Carlson (b) (4)	25 Feb 2021 22:17:18
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'Oral (ORAL)'	Katrina Carlson (b) (4)	25 Feb 2021 22:17:18
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered empty.	Katrina Carlson (b) (4)	25 Feb 2021 22:17:18
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered '19 Feb 2021'	Katrina Carlson (b) (4)	25 Feb 2021 22:17:18
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered '0'	Katrina Carlson (b) (4)	25 Feb 2021 22:17:18
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'Yes (Y)'	Katrina Carlson (b) (4)	25 Feb 2021 22:17:18
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered empty.	Katrina Carlson (b) (4)	25 Feb 2021 22:17:18
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'No (N)'	Katrina Carlson (b) (4)	25 Feb 2021 22:17:18
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 22:17:18

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 22:17:18

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Feb 2021 22:17:18

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
	(b) (4), (b) (6)	01 Mar 2021 19:37:31
DataPoint Verified.	Coder Import (b) (4)	25 Feb 2021 22:36:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 22:36:01
Data point term sent to Coder User entered 'metoprolol'	System Katrina Carlson (b) (4)	25 Feb 2021 22:20:01 25 Feb 2021 22:19:00

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'No (N)'	Katrina Carlson (b) (4)	25 Feb 2021 22:19:00
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
	(b) (4), (b) (6)	01 Mar 2021 19:37:31
DataPoint Verified.		
User entered 'hypertension'	Katrina Carlson (b) (4)	25 Feb 2021 22:19:00
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered '50'	Katrina Carlson (b) (4)	25 Feb 2021 22:19:00
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'mg (mg)'	Katrina Carlson (b) (4)	25 Feb 2021 22:19:00
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered empty.	Katrina Carlson (b) (4)	25 Feb 2021 22:19:00
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'twice daily (BID)'	Katrina Carlson (b) (4)	25 Feb 2021 22:19:00
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered empty.	Katrina Carlson (b) (4)	25 Feb 2021 22:19:00
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'Oral (ORAL)'	Katrina Carlson (b) (4)	25 Feb 2021 22:19:00
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered empty.	Katrina Carlson (b) (4)	25 Feb 2021 22:19:00
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered '19 Feb 2021'	Katrina Carlson (b) (4)	25 Feb 2021 22:19:00
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered '0'	Katrina Carlson (b) (4)	25 Feb 2021 22:19:00
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'Yes (Y)'	Katrina Carlson (b) (4)	25 Feb 2021 22:19:00
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered empty.	Katrina Carlson (b) (4)	25 Feb 2021 22:19:00
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'No (N)'	Katrina Carlson (b) (4)	25 Feb 2021 22:19:00
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Feb 2021 22:19:00

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 22:19:00

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Feb 2021 22:19:00

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
	(b) (4), (b) (6)	01 Mar 2021 19:37:31
DataPoint Verified.	Coder Import (b) (4)	25 Feb 2021 22:22:03
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TICAGRELOR, PRODUCTSYNONYM: BRILINTA - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 22:22:03
	(b) (4)	
Data point term sent to Coder	System	25 Feb 2021 22:21:02
User entered 'brilinta'	Katrina Carlson (b) (4)	25 Feb 2021 22:20:55
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'No (N)'	Katrina Carlson (b) (4)	25 Feb 2021 22:20:55
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
	(b) (4), (b) (6)	13 Apr 2021 09:30:15
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	Taylor Atkinson (b) (4)	09 Apr 2021 17:57:27
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'As per subject, this is the indication the medication was prescribed for in order to reduce future heart risks' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 12:15:34
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'hyperlipidemia'	Katrina Carlson (b) (4)	25 Feb 2021 22:20:55
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered '90'	Katrina Carlson (b) (4)	25 Feb 2021 22:20:55
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'mg (mg)'	Katrina Carlson (b) (4)	25 Feb 2021 22:20:55
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered empty.	Katrina Carlson (b) (4)	25 Feb 2021 22:20:55
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'twice daily (BID)'	Katrina Carlson (b) (4)	25 Feb 2021 22:20:55
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered empty.	Katrina Carlson (b) (4)	25 Feb 2021 22:20:55
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'Oral (ORAL)'	Katrina Carlson (b) (4)	25 Feb 2021 22:20:55
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered empty.	Katrina Carlson (b) (4)	25 Feb 2021 22:20:55
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered '19 Feb 2021'	Katrina Carlson (b) (4)	25 Feb 2021 22:20:55
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered '0'	Katrina Carlson (b) (4)	25 Feb 2021 22:20:55
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'Yes (Y)'	Katrina Carlson (b) (4)	25 Feb 2021 22:20:55
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered empty.	Katrina Carlson (b) (4)	25 Feb 2021 22:20:55
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'No (N)'	Katrina Carlson (b) (4)	25 Feb 2021 22:20:55
	(b) (4)	

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Feb 2021 22:20:55

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 22:20:55

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Feb 2021 22:20:55

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:50:00
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN, PRODUCTSYNONYM: LEVOQUIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 11:22:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 11:22:45
Data point term sent to Coder Coding entries removed.	System Bram Swarr (b) (4)	08 Mar 2021 17:18:19 08 Mar 2021 17:17:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN, PRODUCTSYNONYM: LEVOQUIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 11:12:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 11:12:15
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
Data point term sent to Coder User entered 'levoquin'	System Katrina Carlson (b) (4)	25 Feb 2021 22:48:40 25 Feb 2021 22:47:43

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:50:00
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'No (N)'	Katrina Carlson (b) (4)	25 Feb 2021 22:47:43

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:50:00
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
User closed query 'please add what type of infection to the term.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 20:03:19
Query 'please add what type of infection to the term.' answered with 'Lung infection - this will be updated when medical records are received' (Site from CRA).	Taylor Atkinson (b) (4)	09 Apr 2021 18:03:30
DataPoint Un-verified.	Bram Swarr (b) (4)	08 Mar 2021 17:17:26
User entered 'INFECTION (lower lobes of lungs)' reason for change: Data Entry Error	Bram Swarr (b) (4)	08 Mar 2021 17:17:26
User opened query 'please add what type of infection to the term.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:09:22
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'infection'	Katrina Carlson (b) (4)	25 Feb 2021 22:47:43

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:50:00
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered '750'	Katrina Carlson (b) (4)	25 Feb 2021 22:47:43

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:50:00
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'mg (mg)'	Katrina Carlson (b) (4)	25 Feb 2021 22:47:43

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:50:00
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered empty.	Katrina Carlson (b) (4)	25 Feb 2021 22:47:43

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:50:00
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'once daily (QD)'	Katrina Carlson (b) (4)	25 Feb 2021 22:47:43

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:50:00
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered empty.	Katrina Carlson (b) (4)	25 Feb 2021 22:47:43

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:50:00
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'Oral (ORAL)'	Katrina Carlson (b) (4)	25 Feb 2021 22:47:43

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:50:00
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered empty.	Katrina Carlson (b) (4)	25 Feb 2021 22:47:43

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:50:00
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered '19 Feb 2021'	Katrina Carlson (b) (4)	25 Feb 2021 22:47:43

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:50:00
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered '0'	Katrina Carlson (b) (4)	25 Feb 2021 22:47:43

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:50:00
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'No (N)'	Katrina Carlson (b) (4)	25 Feb 2021 22:47:43

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:50:00
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered '24 Feb 2021'	Katrina Carlson (b) (4)	25 Feb 2021 22:47:43

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:50:00
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:37:31
User entered 'No (N)'	Katrina Carlson (b) (4)	25 Feb 2021 22:47:43

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:50:00
User entered '1'	System	25 Feb 2021 22:47:43

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:50:00
User entered '1'	System	25 Feb 2021 22:47:43

US3902020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:50:00
User entered '804 (804)'	System	25 Feb 2021 22:47:43

US3902020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:16:35

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
	(b) (4), (b) (6)	09 Apr 2021 20:03:44
User closed query 'please obtain medical records from hospital including the medication administration record and the cardiac cath report. Please confirm if cardiac stent placement should be added.' (Site from CRA).	Taylor Atkinson (b) (4)	09 Apr 2021 17:53:18
Query 'please obtain medical records from hospital including the medication administration record and the cardiac cath report. Please confirm if cardiac stent placement should be added.' answered with 'Site to update pending medical records' (Site from CRA).	(b) (4)	
User opened query 'please obtain medical records from hospital including the medication administration record and the cardiac cath report. Please confirm if cardiac stent placement should be added.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 18:09:56
User entered 'No (N)'	Bram Swarr (b) (4)	02 Mar 2021 19:14:44

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'USA-US210-2021-MRNA-1273-P301000001'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'Yes (Y)'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'No (N)'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'No (N)'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'Yes (Y)'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'No (N)'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'No (N)'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'No (N)'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'Murray'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'Kimmel'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'US'	System	26 Feb 2021 15:37:01

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Apr 2021 14:01:11
User entered '1'	System	26 Feb 2021 15:37:01

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'USA-US210-2021-MRNA-1273-P301000001'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Serious](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'Yes (Y)'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'No (N)'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'No (N)'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'Yes (Y)'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'No (N)'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'No (N)'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'No (N)'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'Murray'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'Kimmel'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'US'	System	26 Feb 2021 15:37:01

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Apr 2021 14:01:11
User entered '1'	System	26 Feb 2021 15:37:01

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:16:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered '26/Feb/2021 10:36'	System	26 Feb 2021 15:37:01

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:16:35

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)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'I'	(b) (4), (b) (6)	26 Feb 2021 15:37:01

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'USA-US210-2021-MRNA-1273-P301000001'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'Yes (Y)'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'No (N)'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'No (N)'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'Yes (Y)'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'No (N)'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'No (N)'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'No (N)'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'Murray'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'Kimmel'	System	26 Feb 2021 15:27:33

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:00:59
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:12:04
User entered 'US'	System	26 Feb 2021 15:37:01

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Apr 2021 14:01:11
User entered '1'	System	26 Feb 2021 15:37:01

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:16:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	23 Apr 2021 17:08:39
User entered '21/Apr/2021 09:01'	System	21 Apr 2021 14:01:11

US3902020

Folder: SAE USA-US210-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:16:35

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)	23 Apr 2021 17:08:39
User entered 'I'	(b) (4), (b) (6)	21 Apr 2021 14:01:11