

US3892054 (Prod: Synexus Clinical Research US, Inc. - Salt Lake City)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:23:48

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US3892054

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 18:30:17

Generated On: 10 Jun 2021 10:23:48

[Participant ID](#)

US3892054

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

US3892054

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 18:30:18

Generated On: 10 Jun 2021 10:23:48

Date of Birth (MMM yyyy)	(b) (6) 1979
Age	41
Age Units	YEARS
Age (Derived)	41
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 18:30:43

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Date of Informed Consent (<i>dd MMM yyyy</i>)	4 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) 23 Feb 2021 18:30:43

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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) 23 Feb 2021 18:30:43

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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) 23 Feb 2021 18:30:43

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Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

Condition	SMOKER
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Start Year (derived)	1996
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

Condition	STRANGULATED BOWEL
Start date (dd MMM yyyy)	UN FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN FEB 2020
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	FEB 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

Condition	LEFT OSTEOARTHRITIS HIP
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Start Year (derived)	1997
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

Condition	DERMAL FUNGAL INFECTION
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Start Year (derived)	1997
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	04 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	12:40 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 12:40
Height (<i>xxx.x</i>)	163.5 cm
Weight (<i>xxx.x</i>)	51.3 kg
BMI (<i>xxx.x</i>)	19.19030 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) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 23 Feb 2021 18:30:18

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Date of assessment (dd MMM yyyy) 04 SEP 2020

Is the participant of childbearing potential? Yes ☒
No ☐

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☐
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 18:30:43

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Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	04 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 18:30:43

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 18:30:43

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 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) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

What was the date of randomization? (dd MMM yyyy) 04 SEP 2020

What was the participant's randomization number? 112037

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) 23 Feb 2021 18:30:43

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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) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

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)	04 SEP 2020
Time of assessment (00:00-23:59)	12:40 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 12:40
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)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

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)	04 SEP 2020
Time of assessment (00:00-23:59)	14:52 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 14:52
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

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) 4 SEP 2020

What was the treatment time? (00:00-23:59) 14:18 (24 HR)

Treatment Date and Time (derived) 4 SEP 2020 14:18

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) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 SEP 2020
Collection time (00:00-23:59)	13:58 (24 HR)
Collection date and time (derived)	4 SEP 2020 13:58

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

Collection date (dd MMM yyyy)			04 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:52	04 SEP 2020 13:52
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

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 10:23:48

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

98.9 °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

04 SEP 2020 14:52

PC Open Date & Time

04 SEP 2020 14:38

PC Close Date & Time

04 SEP 2020 17:08

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °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	05 SEP 2020 11:40
PC Open Date & Time	04 SEP 2020 18:03
PC Close Date & Time	05 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

06 SEP 2020 10:59

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

07 SEP 2020 10:42

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(4)

Generated On: 10 Jun 2021 10:23:48

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

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

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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 14:45

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:23:48

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

95.0 °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

09 SEP 2020 13:28

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 14:40

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

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

04 SEP 2020 14:53

PC Open Date & Time

04 SEP 2020 14:38

PC Close Date & Time

04 SEP 2020 17:08

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

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

3

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 11:43

PC Open Date & Time

04 SEP 2020 18:03

PC Close Date & Time

05 SEP 2020 11:59

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:48

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

3

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

06 SEP 2020 10:59

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:23:48

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

07 SEP 2020 10:42

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:48

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 ☐

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

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:48

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

08 SEP 2020 14:46

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:48

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

09 SEP 2020 13:29

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:23:48

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

10 SEP 2020 14:40

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 14:53
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PC Open Date & Time	04 SEP 2020 14:38
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PC Close Date & Time	04 SEP 2020 17:08
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US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

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

No ☒

Yes ☐

PC Time stamp	05 SEP 2020 11:44
PC Open Date & Time	04 SEP 2020 18:03
PC Close Date & Time	05 SEP 2020 11:59

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:48

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 10:59
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:48

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 ☒

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:48

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 10:43
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:48

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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Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:48

Yes ☐

PC Time stamp

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:48

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 14:46
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:48

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 13:29
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 1948

EAB) (1725)

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:48

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 14:41
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3892054

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:30:18

Generated On: 10 Jun 2021 10:23:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892054

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:30:18

Generated On: 10 Jun 2021 10:23:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892054

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:30:18

Generated On: 10 Jun 2021 10:23:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892054

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:30:18

Generated On: 10 Jun 2021 10:23:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892054

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:30:18

Generated On: 10 Jun 2021 10:23:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892054

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:30:18

Generated On: 10 Jun 2021 10:23:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892054

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

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 OCT 2020
Time of assessment (00:00-23:59)	11:55 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 11:55
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	109 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

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)	02 OCT 2020
Time of assessment (00:00-23:59)	14:09 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 14:09
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)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3892054

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 OCT 2020

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

US3892054

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	02 OCT 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3892054

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

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) 02 OCT 2020

What was the treatment time? (00:00-23:59) 13:37 (24 HR)

Treatment Date and Time (derived) 02 OCT 2020 13:37

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

US3892054

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 OCT 2020
Collection time (00:00-23:59)	12:57 (24 HR)
Collection date and time (derived)	02 OCT 2020 12:57

US3892054

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

Collection date (dd MMM yyyy)			02 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:16	02 OCT 2020 12:16
Nasopharyngeal Swab 2	No		

US3892054

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

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

02 OCT 2020 14:12

PC Open Date & Time

02 OCT 2020 13:57

PC Close Date & Time

02 OCT 2020 16:27

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

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 97.2 °F

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

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

PC Time Stamp	03 OCT 2020 06:55
PC Open Date & Time	02 OCT 2020 17:22
PC Close Date & Time	03 OCT 2020 11:59

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:23:48

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

97.9 °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 15:00

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 16:12

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:23:48

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

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

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:23:48

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

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:23:48

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.

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 21:24

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

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

02 OCT 2020 14:12

PC Open Date & Time

02 OCT 2020 13:57

PC Close Date & Time

02 OCT 2020 16:27

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

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 OCT 2020 06:55

PC Open Date & Time

02 OCT 2020 17:22

PC Close Date & Time

03 OCT 2020 11:59

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:48

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

2

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

03 OCT 2020 15:01

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:23:48

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

04 OCT 2020 16:12

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:48

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 ☐

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

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:48

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

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:23:48

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 OCT 2020 21:24

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 14:13
PC Open Date & Time	02 OCT 2020 13:57
PC Close Date & Time	02 OCT 2020 16:27

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

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

No ☒

Yes ☐

PC Time stamp	03 OCT 2020 06:56
PC Open Date & Time	02 OCT 2020 17:22
PC Close Date & Time	03 OCT 2020 11:59

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:48

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 15:01
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:48

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)

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:48

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 16:13
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:48

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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Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:48

Yes ☐

PC Time stamp

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:48

Yes ☐

PC Time stamp

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:48

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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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:48

Yes ☐

PC Time stamp

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:48

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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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:48

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 21:25
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3892054

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:30:18

Generated On: 10 Jun 2021 10:23:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 OCT 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

If Contact Not Made, please provide Comments

MADE THREE ATTEMPTS ON
THE DAY 09 OCT. 2020, AND
ANOTHER ON THE DAY 15 OCT.
2020. NO RESPONSE.

US3892054

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:30:18

Generated On: 10 Jun 2021 10:23:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892054

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:30:18

Generated On: 10 Jun 2021 10:23:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892054

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:30:18

Generated On: 10 Jun 2021 10:23:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892054

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:30:18

Generated On: 10 Jun 2021 10:23:48

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

US3892054

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:30:18

Generated On: 10 Jun 2021 10:23:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892054

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3892054

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	30 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:14 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 11:14
Temperature (<i>xxx.x</i>)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	84 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
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)	

US3892054

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 OCT 2020

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

US3892054

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 OCT 2020
Collection time (00:00-23:59)	11:36 (24 HR)
Collection date and time (derived)	30 OCT 2020 11:36

US3892054

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:30:43

Generated On: 10 Jun 2021 10:23:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892054

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 11:30:59

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3892054

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 07:52:34

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3892054

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 00:02:08

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 NOV 2020 11:49:25
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 19:39:01

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 DEC 2020 13:23:24
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 DEC 2020 16:11:07

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 DEC 2020 09:30:57

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 18:26:45

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 11:17:32

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 15:28:11

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 JAN 2021 07:41:24

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 16:41:55

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 09:29:05

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 FEB 2021 09:50:03

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 FEB 2021 19:39:55

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 FEB 2021 00:08:58

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 00:55:37

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	08 MAR 2021 08:48:04
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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="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"/>

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 <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"/>

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

21 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 09:38:41

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 13:10:18

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

11 APR 2021 19:12:51

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

20 APR 2021 11:10:20

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

26 APR 2021 23:08:06

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 05:25:53

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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"/>

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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"/>

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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"/>

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 362

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
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Patient Cloud Close Date & Time	09 SEP 2021 23:59
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US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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"/>

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	28 OCT 2021 23:59
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US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
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Patient Cloud Close Date & Time	18 NOV 2021 23:59
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US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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"/>

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 DEC 2021 00:01
Patient Cloud Close Date & Time	23 DEC 2021 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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"/>

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 <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"/>

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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"/>

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

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03 MAR 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

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10 MAR 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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°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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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"/>

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	28 APR 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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"/>

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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"/>

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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"/>

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 SEP 2022 00:01
Patient Cloud Close Date & Time	29 SEP 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

DAY 768

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

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

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

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

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

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

Date and time of submission

Patient Cloud Open Date & Time	23 OCT 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	27 OCT 2022 23:59
---	-------------------

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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 ☐

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3892054

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:23:48

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 00:55:48

US3892054

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:30:18

Generated On: 10 Jun 2021 10:23:48

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

US3892054

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:30:18

Generated On: 10 Jun 2021 10:23:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892054

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:30:18

Generated On: 10 Jun 2021 10:23:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892054

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:30:18

Generated On: 10 Jun 2021 10:23:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892054

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:30:18

Generated On: 10 Jun 2021 10:23:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892054

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:30:18

Generated On: 10 Jun 2021 10:23:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892054

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 16:27:14

Generated On: 10 Jun 2021 10:23:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892054

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 16:27:14

Generated On: 10 Jun 2021 10:23:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892054

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 16:27:14

Generated On: 10 Jun 2021 10:23:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3892054

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 16:27:14

Generated On: 10 Jun 2021 10:23:48

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) _____

US3892054

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 16:27:14

Generated On: 10 Jun 2021 10:23:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 APR 2021

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

US3892054

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 16:27:14

Generated On: 10 Jun 2021 10:23:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 APR 2021
Collection time (00:00-23:59)	11:33 (24 HR)
Collection date and time (derived)	2 APR 2021 11:33

US3892054

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 16:27:14

Generated On: 10 Jun 2021 10:23:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892054

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892054

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3892054

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:23:48

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 10:23:48

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3892054

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:30:18

Generated On: 10 Jun 2021 10:23:48

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

Visit date (dd MMM yyyy)	14 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3892054

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 16:27:14

Generated On: 10 Jun 2021 10:23:48

Date of updated informed consent (*dd MMM yyyy*) 14 JAN 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*) 14 JAN 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 _____

US3892054

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:30:17

Generated On: 10 Jun 2021 10:23:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 JAN 2021

Collection time (00:00-23:59)

15:44 (24 HR)

Collection date and time (derived)

14 JAN 2021 15:44

US3892054

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 18:30:17

Generated On: 10 Jun 2021 10:23:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	15:53
Collection Date and Time (derived)	14 JAN 2021 15:53

US3892054

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 16:22:01

Generated On: 10 Jun 2021 10:23:48

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3892054

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Apr 2021 16:03:28

Generated On: 10 Jun 2021 10:23:48

AEID	USA-US209-2021-MRNA-1273-P30 1000004
Adverse event	WORSENING OF DEPRESSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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)	20 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	25 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Apr 2021 16:03:28

Generated On: 10 Jun 2021 10:23:48

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	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	

US3892054

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Apr 2021 16:03:28

Generated On: 10 Jun 2021 10:23:48

SUBJECT REPORTS
SIGNIFICANT STRESS
INCLUDING FINANCIAL, LEGAL
AND RELATIONSHIP,
EMOTIONAL ISSUES. THIS LED
HER TO FEEL THAT SHE
NEEDED "A BREAK FROM
LIFE." SHE HAD SUICIDAL
IDEATIONS AND WAS
ADMITTED TO A MENTAL
HEALTH INPATIENT HOSPITAL
FROM 20MAR2021 TO
25MAR2021. DURING THIS
ADMISSION, CELEXA WAS
STOPPED AND PAROXETINE
WAS STARTED. BUSPIRONE
WAS INCREASED FROM 20 MG
BID TO 30 MG BID. SHE
CURRENTLY HAS NO SUICIDAL
IDEATIONS. SHE REPORTS
SOME DEPRESSION, INSOMNIA,
FATIGUE, POOR
CONCENTRATION, AND
FEELING OVERWHELMED BUT
THESE SYMPTOMS ARE MUCH
IMPROVED FROM 2 WEEKS
AGO.

15 APR 21: PER MEDICAL
RECORDS SYMPTOMS
RETURNED TO BASELINE UPON
DISCHARGE.

21 MAR 2021: SPECIMEN
COLLECTED - SALIVA.
22 MAR 2021 - COVID19 PCR
NOT DETECTED

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

US3892054

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Apr 2021 16:03:28

Generated On: 10 Jun 2021 10:23:48

AEID	
Adverse event	WORSENING OF ANXIETY
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)	17 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3892054

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Apr 2021 16:03:28

Generated On: 10 Jun 2021 10:23:48

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

US3892054

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Apr 2021 16:03:28

Generated On: 10 Jun 2021 10:23:48

AEID	
Adverse event	URINARY TRACT INFECTION
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)	24 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Apr 2021 16:03:28

Generated On: 10 Jun 2021 10:23:48

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

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 18:30:17

Generated On: 10 Jun 2021 10:23:48

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

Yes ☒

No ☐

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

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Apr 2021 16:03:28

Generated On: 10 Jun 2021 10:23:48

Name of Medication ABILIFY

Prophylaxis Yes ☐

No ☒

Indication DEPRESSION

Dose per administration 10

Dose unit mg ☒

ug ☐

mL ☐

g ☐

IU ☐

tablet ☐

capsule ☐

puff ☐

Other ☐

If dose unit is Other, specify

Frequency once daily ☒

twice daily ☐

three times daily ☐

four times daily ☐

every other day ☐

every week ☐

every month ☐

as needed ☐

once ☐

unknown ☐

other ☐

If frequency is Other, specify

Route of administration Oral ☒

Topical ☐

Subcutaneous ☐

Transdermal ☐

Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Apr 2021 16:03:28

Generated On: 10 Jun 2021 10:23:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Apr 2021 16:03:28

Generated On: 10 Jun 2021 10:23:48

Name of Medication CELEXA

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Apr 2021 16:03:28

Generated On: 10 Jun 2021 10:23:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	10 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"/>

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Apr 2021 16:03:28

Generated On: 10 Jun 2021 10:23:48

Name of Medication VISTARIL

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

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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US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Apr 2021 16:03:28

Generated On: 10 Jun 2021 10:23:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Apr 2021 16:03:28

Generated On: 10 Jun 2021 10:23:48

Name of Medication NORETHINDRONE

Prophylaxis Yes ☒
No ☐

Indication BIRTH CONTROL

Dose per administration 0.35

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Apr 2021 16:03:28

Generated On: 10 Jun 2021 10:23:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Apr 2021 16:03:28

Generated On: 10 Jun 2021 10:23:48

Name of Medication BUSPIRONE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF ANXIETY

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Apr 2021 16:03:28

Generated On: 10 Jun 2021 10:23:48

	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)	17 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Apr 2021 16:03:28

Generated On: 10 Jun 2021 10:23:48

Name of Medication CELEXA

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF DEPRESSION

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 (6)

Data signed: (b) (4) 19 Apr 2021 16:03:28

Generated On: 10 Jun 2021 10:23:48

	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)	10 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) 21 MAR 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"/>

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Apr 2021 16:03:28

Generated On: 10 Jun 2021 10:23:48

Name of Medication PAXIL

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF DEPRESSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Apr 2021 16:03:28

Generated On: 10 Jun 2021 10:23:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 MAR 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"/>

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Apr 2021 16:03:28

Generated On: 10 Jun 2021 10:23:48

Name of Medication BUSPIRONE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF ANXIETY

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Apr 2021 16:03:28

Generated On: 10 Jun 2021 10:23:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 MAR 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"/>

US3892054

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 18:30:17

Generated On: 10 Jun 2021 10:23:48

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:23:48

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3892054

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:23:48

Date of study discontinuation/completion (<i>dd MMM yyyy</i>)	
Reason for discontinuation	AE (specify) <input type="checkbox"/>
	SAE (specify) <input type="checkbox"/>
	Complete <input type="checkbox"/>
	Death <input type="checkbox"/>
	Lost To Follow-up <input type="checkbox"/>
	Physician decision (specify) <input type="checkbox"/>
	Pregnancy <input type="checkbox"/>
	Protocol deviation (specify) <input type="checkbox"/>
	Study Terminated By Sponsor <input type="checkbox"/>
	Withdrawal of consent by participant (specify) <input type="checkbox"/>
	Other <input type="checkbox"/>
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 <input type="checkbox"/>
	Unknown <input type="checkbox"/>
	Other <input type="checkbox"/>
If main cause of death is Other, specify	
Date of death (<i>dd MMM yyyy</i>)	
Was autopsy performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
	Unknown <input type="checkbox"/>

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 19 Apr 2021 16:03:28

Generated On: 10 Jun 2021 10:23:48

SAEID	USA-US209-2021-MRNA-1273-P301000004
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	MICHAEL
Investigator's Last Name	ADAMS
Site Address: Street	5251 S GREEN ST
Site Address: City	MURRAY
Site Address: State	UT
Site Address: Postal Code	84123
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Apr 2021 16:03:28

Generated On: 10 Jun 2021 10:23:48

SAEID	USA-US209-2021-MRNA-1273-P301000004
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	MICHAEL
Investigator's Last Name	ADAMS
Site Address: Street	5251 S GREEN ST
Site Address: City	MURRAY
Site Address: State	UT
Site Address: Postal Code	84123
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	05/APR/2021 11:20
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

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Apr 2021 16:03:28

Generated On: 10 Jun 2021 10:23:48

SAEID	USA-US209-2021-MRNA-1273-P301000004
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	MICHAEL
Investigator's Last Name	ADAMS
Site Address: Street	5251 S GREEN ST
Site Address: City	MURRAY
Site Address: State	UT
Site Address: Postal Code	84123
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	16/APR/2021 11:55
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

US3892054 (Prod: Synexus Clinical Research US, Inc. - Salt Lake City)

US3892054

Form: Participant Creation

Generated On: 10 Jun 2021 10:23:48

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'US3892054'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 18:09:24

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Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:23:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:16:34

US3892054

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '04 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 18:09:25

US3892054

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:23:48

[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 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Clinic (Clinic)'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:16:34

US3892054

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:23:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered 'SCRN'	System	04 Sep 2020 20:16:34

US3892054

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:48

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered (b) (6) 1979'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 18:09:26

US3892054

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:48

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered '41'	(b) (4) Stefanie Vasconez (b) (4)	04 Sep 2020 20:16:47

US3892054

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:48

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered 'YEARS'	System	04 Sep 2020 20:16:47

US3892054

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:48

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered '41'	System	04 Sep 2020 20:17:02

US3892054

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:48

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Female (F)'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:16:47

US3892054

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:48

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Stefanie Vasconez (b) (4)	04 Sep 2020 20:16:47

US3892054

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:48

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'I'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:16:47

US3892054

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:48

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered '0'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:16:47

US3892054

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:48

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered '0'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:16:47

US3892054

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:48

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered '0'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:16:47

US3892054

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:48

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered '0'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:16:47

US3892054

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered '0'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:16:47

US3892054

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:48

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered empty.	(b) (4) Stefanie Vasconez (b) (4)	04 Sep 2020 20:16:47

US3892054

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:48

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered '0'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:16:47

US3892054

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:48

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered '0'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:16:47

US3892054

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '4 Sep 2020'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:02

US3892054

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered 'Sep 2020'	System	04 Sep 2020 20:17:02

US3892054

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered '2020'	System	04 Sep 2020 20:17:02

US3892054

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:23:48

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Amendment 3 (3)'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:02

US3892054

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:02

US3892054

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:02

US3892054

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:23:48

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	(b) (4) Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:02

US3892054

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:23:48

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'No (N)'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:02

US3892054

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:23:48

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 18:09:25

US3892054

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:23:48

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered 'I'	System	04 Sep 2020 20:17:09

US3892054

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:09

US3892054

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:23:48

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:56:48

US3892054

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:23:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 21:58:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 21:58:56
Data point term sent to Coder	System	02 Oct 2020 21:57:51
User entered 'Depression'	Andryelle Toledo (b) (4)	02 Oct 2020 21:57:18

US3892054

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'un UNK 1995'	Andryelle Toledo (b) (4)	02 Oct 2020 21:57:18

US3892054

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:23:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '0'	Andryelle Toledo (b) (4)	02 Oct 2020 21:57:18

US3892054

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:23:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:57:18

US3892054

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	Andryelle Toledo (b) (4)	02 Oct 2020 21:57:18

US3892054

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:23:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '0'	Andryelle Toledo (b) (4)	02 Oct 2020 21:57:18

US3892054

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered 'Jan 1995'	System	02 Oct 2020 21:57:18

US3892054

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered '1995'	System	02 Oct 2020 21:57:18

US3892054

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered empty.	System	02 Oct 2020 21:57:18

US3892054

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered empty.	System	02 Oct 2020 21:57:18

US3892054

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:23:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 21:58:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 21:58:56
Data point term sent to Coder	System	02 Oct 2020 21:57:51
User entered 'Anxiety'	Andryelle Toledo (b) (4)	02 Oct 2020 21:57:37
	(b) (4)	

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Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'un UNK 2009'	Andryelle Toledo (b) (4)	02 Oct 2020 21:57:37

US3892054

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:23:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '0'	Andryelle Toledo (b) (4)	02 Oct 2020 21:57:37

US3892054

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:23:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 21:57:37

US3892054

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	Andryelle Toledo (b) (4)	02 Oct 2020 21:57:37

US3892054

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:23:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '0'	Andryelle Toledo (b) (4)	02 Oct 2020 21:57:37

US3892054

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered 'Jan 2009'	System	02 Oct 2020 21:57:37

US3892054

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered '2009'	System	02 Oct 2020 21:57:37

US3892054

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered empty.	System	02 Oct 2020 21:57:37

US3892054

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered empty.	System	02 Oct 2020 21:57:37

US3892054

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:23:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User coded data point as SOC: Social circumstances, HLT: Tobacco use, PT: Tobacco user, LLT: Smoker - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 21:59:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 21:59:52
Data point term sent to Coder	System	02 Oct 2020 21:58:52
User entered 'Smoker'	Andryelle Toledo (b) (4)	02 Oct 2020 21:57:52

US3892054

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'un UNK 1996'	Andryelle Toledo (b) (4)	02 Oct 2020 21:57:52

US3892054

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:23:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '0'	Andryelle Toledo (b) (4)	02 Oct 2020 21:57:52

US3892054

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:23:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:57:52

US3892054

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	Andryelle Toledo (b) (4)	02 Oct 2020 21:57:52

US3892054

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:23:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '0'	Andryelle Toledo (b) (4)	02 Oct 2020 21:57:52

US3892054

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered 'Jan 1996'	System	02 Oct 2020 21:57:52

US3892054

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered '1996'	System	02 Oct 2020 21:57:52

US3892054

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered empty.	System	02 Oct 2020 21:57:52

US3892054

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered empty.	System	02 Oct 2020 21:57:52

US3892054

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:23:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal stenosis and obstruction, HLT: Gastrointestinal stenosis and obstruction NEC, PT: Intestinal strangulation, LLT: Intestinal strangulation - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 04:30:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 04:30:50
Data point term sent to Coder	System	02 Oct 2020 22:00:54
User entered 'Strangulated Bowel'	Andryelle Toledo (b) (4)	02 Oct 2020 22:00:29

US3892054

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'un Feb 2020'	Andryelle Toledo (b) (4)	02 Oct 2020 22:00:29

US3892054

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:23:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '0'	Andryelle Toledo (b) (4)	02 Oct 2020 22:00:29

US3892054

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:23:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:00:29

US3892054

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'un Feb 2020'	Andryelle Toledo (b) (4)	02 Oct 2020 22:00:29

US3892054

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:23:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '0'	Andryelle Toledo (b) (4)	02 Oct 2020 22:00:29

US3892054

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered 'Feb 2020'	System	02 Oct 2020 22:00:29

US3892054

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered '2020'	System	02 Oct 2020 22:00:29

US3892054

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered 'Feb 2020'	System	02 Oct 2020 22:00:29

US3892054

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered '2020'	System	02 Oct 2020 22:00:29

US3892054

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:23:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 07:01:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 07:01:43
Data point term sent to Coder	System	02 Oct 2020 22:01:57
User entered 'left osteoarthritis Hip'	Andryelle Toledo (b) (4)	02 Oct 2020 22:01:12

US3892054

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'un UNK 1997'	Andryelle Toledo (b) (4)	02 Oct 2020 22:01:12

US3892054

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:23:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '0'	Andryelle Toledo (b) (4)	02 Oct 2020 22:01:12

US3892054

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:23:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:01:12

US3892054

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	Andryelle Toledo (b) (4)	02 Oct 2020 22:01:12

US3892054

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:23:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '0'	Andryelle Toledo (b) (4)	02 Oct 2020 22:01:12

US3892054

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered 'Jan 1997'	System	02 Oct 2020 22:01:12

US3892054

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered '1997'	System	02 Oct 2020 22:01:12

US3892054

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered empty.	System	02 Oct 2020 22:01:12

US3892054

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered empty.	System	02 Oct 2020 22:01:12

US3892054

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:23:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Fungal infections NEC, PT: Fungal skin infection, LLT: Fungal skin infection - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 07:14:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 07:14:41
Data point term sent to Coder	System	02 Oct 2020 22:05:01
User entered 'dermal fungal infection'	Andryelle Toledo (b) (4)	02 Oct 2020 22:04:09

US3892054

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'un UNK 1997'	Andryelle Toledo (b) (4)	02 Oct 2020 22:04:09

US3892054

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:23:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '0'	Andryelle Toledo (b) (4)	02 Oct 2020 22:04:09

US3892054

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:23:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Oct 2020 22:04:09

US3892054

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	Andryelle Toledo (b) (4)	02 Oct 2020 22:04:09

US3892054

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:23:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '0'	Andryelle Toledo (b) (4)	02 Oct 2020 22:04:09

US3892054

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered 'Jan 1997'	System	02 Oct 2020 22:04:09

US3892054

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered '1997'	System	02 Oct 2020 22:04:09

US3892054

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered empty.	System	02 Oct 2020 22:04:09

US3892054

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered empty.	System	02 Oct 2020 22:04:09

US3892054

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Oct 2020 22:04:48

US3892054

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '04 Sep 2020'	Andryelle Toledo (b) (4)	02 Oct 2020 22:04:48

US3892054

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '12:40'	Andryelle Toledo (b) (4)	02 Oct 2020 22:04:48

US3892054

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered '04 Sep 2020 12:40'	System	02 Oct 2020 22:04:48

US3892054

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '163.5' cm	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:04:48
DataPoint set to visible.	(b) (4) System	04 Sep 2020 20:17:09

US3892054

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '51.3' kg	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:04:48
DataPoint set to visible.	(b) (4) System	04 Sep 2020 20:17:09

US3892054

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered '19.19030'	System	02 Oct 2020 22:04:48
DataPoint set to visible.	System	04 Sep 2020 20:17:09

US3892054

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered 'kg/m2'	System	02 Oct 2020 22:04:48
DataPoint set to visible.	System	04 Sep 2020 20:17:09

US3892054

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:04:48

US3892054

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	Andryelle Toledo (b) (4)	02 Oct 2020 22:04:48

US3892054

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:04:48

US3892054

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:04:48

US3892054

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered 'bpm'	System	02 Oct 2020 22:04:48

US3892054

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:04:48

US3892054

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered 'breaths/min'	System	02 Oct 2020 22:04:48

US3892054

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered missing code ND - Not Done.	Andryelle Toledo (b) (4)	02 Oct 2020 22:04:48

US3892054

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered 'mmHg'	System	02 Oct 2020 22:04:48

US3892054

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered missing code ND - Not Done.	Andryelle Toledo (b) (4)	02 Oct 2020 22:04:48

US3892054

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered 'mmHg'	System	02 Oct 2020 22:04:48

US3892054

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21

US3892054

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21

US3892054

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:23:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Oct 2020 22:05:35

US3892054

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:23:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '04 Sep 2020'	Andryelle Toledo (b) (4)	02 Oct 2020 22:05:35

US3892054

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:23:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered '04 Sep 2020'	Andryelle Toledo (b) (4)	02 Oct 2020 22:05:55

US3892054

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Oct 2020 22:05:55

US3892054

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered empty.	Andryelle Toledo (b) (4)	02 Oct 2020 22:05:55

US3892054

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:05:55

US3892054

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered empty.	Andryelle Toledo (b) (4)	02 Oct 2020 22:05:55

US3892054

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:23:48

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered '0'	Andryelle Toledo (b) (4)	02 Oct 2020 22:05:55

US3892054

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered empty.	Andryelle Toledo (b) (4)	02 Oct 2020 22:05:55

US3892054

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:23:48

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered '0'	Andryelle Toledo (b) (4)	02 Oct 2020 22:05:55

US3892054

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:23:48

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Oct 2020 22:06:09

US3892054

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:23:48

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '04 Sep 2020'	Andryelle Toledo (b) (4)	02 Oct 2020 22:06:09

US3892054

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:23:48

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Urine (URINE)'	Andryelle Toledo (b) (4)	02 Oct 2020 22:06:09

US3892054

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:23:48

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Negative (NEGATIVE)'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:06:09

US3892054

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:23:48

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Oct 2020 22:06:09

US3892054

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:23:48

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:06:09

US3892054

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:23:48

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	Andryelle Toledo (b) (4)	02 Oct 2020 22:06:09

US3892054

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User entered empty.	System	02 Oct 2020 22:06:09

US3892054

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:48

[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 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'No (N)'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:53

US3892054

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:48

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 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:53

US3892054

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:48

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 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'No (N)'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:53

US3892054

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:48

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 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:53

US3892054

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:48

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 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:53

US3892054

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:48

[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 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'No (N)'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:53

US3892054

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:48

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 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'No (N)'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:53

US3892054

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:48

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 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'No (N)'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:53

US3892054

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:48

[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 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:53

US3892054

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:48

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 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'No (N)'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:53

US3892054

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:48

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 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'No (N)'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:53

US3892054

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:48

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'No (N)'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:53

US3892054

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	(b) (4) Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:53

US3892054

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:48

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '0'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:53

US3892054

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '0'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:53

US3892054

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:48

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 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '0'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:53

US3892054

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:48

[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 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '0'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:53

US3892054

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:48

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 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '0'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:53

US3892054

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '0'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:53

US3892054

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:48

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'I'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:53

US3892054

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:08:21
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'mother in law apartment'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:17:53

US3892054

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:23:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	04 Sep 2020 20:18:07

US3892054

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '4 Sep 2020'	(b) (4) Stefanie Vasconez (b) (4)	04 Sep 2020 20:18:07

US3892054

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Clinic (Clinic)'	(b) (4) Stefanie Vasconez (b) (4)	04 Sep 2020 20:18:07

US3892054

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:23:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'VISIT1'	System	04 Sep 2020 20:18:07

US3892054

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '04 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:49:51

US3892054

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '112037'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:49:51

US3892054

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:49:51

US3892054

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:23:48

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) Stefanie Vasconez (b) (4)	04 Sep 2020 20:18:18

US3892054

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:23:48

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'No (N)'	Stefanie Vasconez (b) (4)	04 Sep 2020 20:18:18

US3892054

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) Stefanie Vasconez (b) (4)	04 Sep 2020 20:18:18

US3892054

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) Stefanie Vasconez (b) (4)	04 Sep 2020 20:18:18

US3892054

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:23:48

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) Stefanie Vasconez (b) (4)	04 Sep 2020 20:18:18

US3892054

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:23:48

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'No (N)'	Andryelle Toledo (b) (4)	30 Sep 2020 23:48:06
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:27:32
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:27:31

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:23:48

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:23:48

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:23:48

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:23:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User accepted default value 'Pre-Dose (PREDOSE)'	Andryelle Toledo (b) (4)	02 Oct 2020 22:08:11
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '04 Sep 2020'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '12:40'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '04 Sep 2020 12:40'	System	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '98.8' F	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Oral (Oral)'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '90'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'bpm'	System	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '16'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'breaths/min'	System	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '123'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'mmHg'	System	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '84'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'mmHg'	System	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:23:48

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:23:48

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User accepted default value 'Post-Dose (POSTDOSE)'	Andryelle Toledo (b) (4) (b) (4)	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '04 Sep 2020'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '14:52'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '04 Sep 2020 14:52'	System	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '98.9' F	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Oral (Oral)'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '92'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'bpm'	System	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '16'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'breaths/min'	System	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '124'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'mmHg'	System	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '83'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'mmHg'	System	02 Oct 2020 22:08:11

US3892054

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:23:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:17

US3892054

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:23:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:17

US3892054

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:23:48

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:25

US3892054

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:23:48

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:25

US3892054

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:23:48

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:25

US3892054

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:23:48

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:25

US3892054

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:23:48

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:25

US3892054

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:23:48

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:25

US3892054

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:23:48

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:08:25

US3892054

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered empty.	System	02 Oct 2020 22:08:25

US3892054

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:23:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	04 Sep 2020 20:29:05

US3892054

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:23:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	(b) (4) Stefanie Vasconez (b) (4)	04 Sep 2020 20:29:05

US3892054

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	(b) (4) Stefanie Vasconez (b) (4)	04 Sep 2020 20:29:05

US3892054

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:23:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 20:29:05

US3892054

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:23:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '4 Sep 2020'	(b) (4) Stefanie Vasconez (b) (4)	04 Sep 2020 20:29:05

US3892054

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '14:18'	(b) (4) Stefanie Vasconez (b) (4)	04 Sep 2020 20:29:05

US3892054

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '4 Sep 2020 14:18'	System	04 Sep 2020 20:29:05

US3892054

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:23:48

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:10:19
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Stefanie Vasconez (b) (4)	04 Sep 2020 20:29:05
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:23:48

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'ONCE'	System	04 Sep 2020 20:29:05

US3892054

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:23:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 20:29:05

US3892054

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	04 Sep 2020 20:29:29

US3892054

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '4 Sep 2020'	(b) (4) Stefanie Vasconez (b) (4)	04 Sep 2020 20:29:29

US3892054

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:48

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '13:58'	(b) (4) Stefanie Vasconez (b) (4)	04 Sep 2020 20:29:29

US3892054

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '4 Sep 2020 13:58'	System	04 Sep 2020 20:29:29

US3892054

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:23:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '04 Sep 2020'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:11:05

US3892054

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:23:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Andryelle Toledo (b) (4)	02 Oct 2020 22:11:05

US3892054

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:23:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:11:05

US3892054

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:23:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '13:52'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:11:05

US3892054

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '04 Sep 2020 13:52'	System	02 Oct 2020 22:11:05

US3892054

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:23:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Andryelle Toledo (b) (4)	02 Oct 2020 22:11:05

US3892054

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:23:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:11:05

US3892054

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:23:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 22:11:05

US3892054

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered empty.	System	02 Oct 2020 22:11:05

US3892054

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	04 Sep 2020 20:29:49

US3892054

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '1'	System	04 Sep 2020 20:29:49

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-04T14:51:57', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'b9dd8e1e-e3a4-4224-a15e-1372af8a0b87'	System	04 Sep 2020 20:52:19
User entered 'Yes (Y)'	System	04 Sep 2020 20:52:19

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-04T14:52:05', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'b9dd8e1e-e3a4-4224-a15e-1372af8a0b87' User entered '98.9'	System	04 Sep 2020 20:52:19
	System	04 Sep 2020 20:52:19

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-04T14:52:12', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'b9dd8e1e-e3a4-4224-a15e-1372af8a0b87'	System	04 Sep 2020 20:52:19
User entered 'No (N)'	System	04 Sep 2020 20:52:19

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-04T14:52:17', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'b9dd8e1e-e3a4-4224-a15e-1372af8a0b87'	System	04 Sep 2020 20:52:19
User entered '04 Sep 2020 14:52'	System	04 Sep 2020 20:52:19

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '04 Sep 2020 14:38'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '04 Sep 2020 17:08'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-05T11:40:24', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'b1365b32-158d-4c34-a345-bf5248b73399'	System	11 Sep 2020 18:10:16
User entered 'Yes (Y)'	System	11 Sep 2020 18:10:16

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-05T11:40:30', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'b1365b32-158d-4c34-a345-bf5248b73399' User entered '98.0'	System	11 Sep 2020 18:10:16
	System	11 Sep 2020 18:10:16

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-05T11:40:34', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'b1365b32-158d-4c34-a345-bf5248b73399'	System	11 Sep 2020 18:10:16
User entered 'No (N)'	System	11 Sep 2020 18:10:16

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-05T11:40:43', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'b1365b32-158d-4c34-a345-bf5248b73399' User entered '05 Sep 2020 11:40'	System	11 Sep 2020 18:10:16
	System	11 Sep 2020 18:10:16

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '04 Sep 2020 18:03'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered 'Day 2'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:23:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-06T10:58:53', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '248082a8-8e97-4b62-979d-b1a0e39254e5' User entered 'Yes (Y)'	System	11 Sep 2020 18:10:20
	System	11 Sep 2020 18:10:20

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:23:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-06T10:58:58', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '248082a8-8e97-4b62-979d-b1a0e39254e5' User entered '98.1'	System	11 Sep 2020 18:10:20
	System	11 Sep 2020 18:10:20

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-06T10:59:02', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '248082a8-8e97-4b62-979d-b1a0e39254e5'	System	11 Sep 2020 18:10:20
User entered 'No (N)'	System	11 Sep 2020 18:10:20

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-06T10:59:05', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '248082a8-8e97-4b62-979d-b1a0e39254e5' User entered '06 Sep 2020 10:59'	System	11 Sep 2020 18:10:20
	System	11 Sep 2020 18:10:20

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered 'Day 3'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:23:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-07T10:41:23', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'b582853e-3bdb-4913-a0a7-371228bd027e' User entered 'Yes (Y)'	System	11 Sep 2020 18:11:16
	System	11 Sep 2020 18:11:16

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:23:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-07T10:42:29', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'b582853e-3bdb-4913-a0a7-371228bd027e' User entered '98.8'	System	11 Sep 2020 18:11:16
	System	11 Sep 2020 18:11:16

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-07T10:42:33', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'b582853e-3bdb-4913-a0a7-371228bd027e' User entered 'No (N)'	System	11 Sep 2020 18:11:16
	System	11 Sep 2020 18:11:16

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-07T10:42:36', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'b582853e-3bdb-4913-a0a7-371228bd027e' User entered '07 Sep 2020 10:42'	System	11 Sep 2020 18:11:16
	System	11 Sep 2020 18:11:16

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered 'Day 4'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:23:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:23:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:23:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered 'Day 5'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:23:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-08T14:45:46', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'ae92f7c8-f718-4bfa-816c-b9716533b7f8' User entered 'Yes (Y)'	System	11 Sep 2020 18:11:28
	System	11 Sep 2020 18:11:28

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:23:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-08T14:45:52', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'ae92f7c8-f718-4bfa-816c-b9716533b7f8' User entered '98.4'	System	11 Sep 2020 18:11:28
	System	11 Sep 2020 18:11:28

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-08T14:45:56', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'ae92f7c8-f718-4bfa-816c-b9716533b7f8'	System	11 Sep 2020 18:11:28
User entered 'No (N)'	System	11 Sep 2020 18:11:28

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-08T14:45:58', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'ae92f7c8-f718-4bfa-816c-b9716533b7f8' User entered '08 Sep 2020 14:45'	System	11 Sep 2020 18:11:28
	System	11 Sep 2020 18:11:28

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered 'Day 6'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:23:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-09T13:27:23', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '61f60861-985e-40a2-83b1-3003f3e1e38d' User entered 'Yes (Y)'	System	11 Sep 2020 18:11:34
	System	11 Sep 2020 18:11:34

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:23:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-09T13:28:35', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '61f60861-985e-40a2-83b1-3003f3e1e38d' User entered '95.0'	System	11 Sep 2020 18:11:34
	System	11 Sep 2020 18:11:34

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-09T13:28:38', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '61f60861-985e-40a2-83b1-3003f3e1e38d' User entered 'No (N)'	System	11 Sep 2020 18:11:34
	System	11 Sep 2020 18:11:34

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-09T13:28:41', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '61f60861-985e-40a2-83b1-3003f3e1e38d' User entered '09 Sep 2020 13:28'	System	11 Sep 2020 18:11:34
	System	11 Sep 2020 18:11:34

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered 'Day 7'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:23:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-10T14:39:25', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'd7488de7-8819-43ee-a1a8-63a1e918f896'	System	11 Sep 2020 18:11:43
User entered 'Yes (Y)'	System	11 Sep 2020 18:11:43

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:23:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-10T14:39:30', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'd7488de7-8819-43ee-a1a8-63a1e918f896'	System	11 Sep 2020 18:11:43
User entered '98.6'	System	11 Sep 2020 18:11:43

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-10T14:40:01', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'd7488de7-8819-43ee-a1a8-63a1e918f896'	System	11 Sep 2020 18:11:43
User entered 'No (N)'	System	11 Sep 2020 18:11:43

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-10T14:40:04', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'd7488de7-8819-43ee-a1a8-63a1e918f896'	System	11 Sep 2020 18:11:43
User entered '10 Sep 2020 14:40'	System	11 Sep 2020 18:11:43

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-04T14:52:31', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '24c8fe2c-f913-4331-9dad-9f8ec318afae'	System	04 Sep 2020 20:53:03
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 20:53:03

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-04T14:52:44', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '24c8fe2c-f913-4331-9dad-9f8ec318afae' User entered 'No (N)'	System	04 Sep 2020 20:53:03
	System	04 Sep 2020 20:53:03

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-04T14:52:48', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '24c8fe2c-f913-4331-9dad-9f8ec318afae' User entered 'No (N)'	System	04 Sep 2020 20:53:03
	System	04 Sep 2020 20:53:03

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-04T14:52:57', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '24c8fe2c-f913-4331-9dad-9f8ec318afae' User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 20:53:03
	System	04 Sep 2020 20:53:03

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-04T14:53:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '24c8fe2c-f913-4331-9dad-9f8ec318afae' User entered '04 Sep 2020 14:53'	System	04 Sep 2020 20:53:03
	System	04 Sep 2020 20:53:03

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '04 Sep 2020 14:38'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '04 Sep 2020 17:08'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-05T11:41:59', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '7b6816a2-bb6d-4f11-bb7b-9a2f5afce886'	System	11 Sep 2020 18:10:17
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 18:10:17

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-05T11:42:02', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '7b6816a2-bb6d-4f11-bb7b-9a2f5afce886'	System	11 Sep 2020 18:10:17
User entered 'No (N)'	System	11 Sep 2020 18:10:17

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-05T11:42:07', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '7b6816a2-bb6d-4f11-bb7b-9a2f5afce886'	System	11 Sep 2020 18:10:17
User entered 'Yes (Y)'	System	11 Sep 2020 18:10:17

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-05T11:43:22', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '7b6816a2-bb6d-4f11-bb7b-9a2f5afce886' User entered '3'	System	11 Sep 2020 18:10:17
	System	11 Sep 2020 18:10:17

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-05T11:43:26', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '7b6816a2-bb6d-4f11-bb7b-9a2f5afce886'	System	11 Sep 2020 18:10:17
User entered 'None (1)'	System	11 Sep 2020 18:10:17

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-05T11:43:44', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '7b6816a2-bb6d-4f11-bb7b-9a2f5afce886' User entered '05 Sep 2020 11:43'	System	11 Sep 2020 18:10:17
	System	11 Sep 2020 18:10:17

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '04 Sep 2020 18:03'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered 'Day 2'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-06T10:59:13', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '4abf6d58-01c3-489a-a0e3-638bd80140ff'	System	11 Sep 2020 18:11:13
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 18:11:13

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-06T10:59:16', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '4abf6d58-01c3-489a-a0e3-638bd80140ff' User entered 'No (N)'	System	11 Sep 2020 18:11:13
	System	11 Sep 2020 18:11:13

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-06T10:59:19', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '4abf6d58-01c3-489a-a0e3-638bd80140ff' User entered 'Yes (Y)'	System	11 Sep 2020 18:11:13
	System	11 Sep 2020 18:11:13

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-06T10:59:26', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '4abf6d58-01c3-489a-a0e3-638bd80140ff' User entered '3'	System	11 Sep 2020 18:11:13
	System	11 Sep 2020 18:11:13

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-06T10:59:31', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '4abf6d58-01c3-489a-a0e3-638bd80140ff' User entered 'None (1)'	System	11 Sep 2020 18:11:13
	System	11 Sep 2020 18:11:13

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-06T10:59:33', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '4abf6d58-01c3-489a-a0e3-638bd80140ff' User entered '06 Sep 2020 10:59'	System	11 Sep 2020 18:11:13
	System	11 Sep 2020 18:11:13

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered 'Day 3'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-07T10:42:41', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '9dd5c0e5-31d7-445a-b3ab-78388c99e952'	System	11 Sep 2020 18:11:28
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 18:11:28

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:23:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-07T10:42:44', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '9dd5c0e5-31d7-445a-b3ab-78388c99e952'	System	11 Sep 2020 18:11:28
User entered 'No (N)'	System	11 Sep 2020 18:11:28

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-07T10:42:49', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '9dd5c0e5-31d7-445a-b3ab-78388c99e952'	System	11 Sep 2020 18:11:28
User entered 'No (N)'	System	11 Sep 2020 18:11:28

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-07T10:42:52', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '9dd5c0e5-31d7-445a-b3ab-78388c99e952'	System	11 Sep 2020 18:11:28
User entered 'None (1)'	System	11 Sep 2020 18:11:28

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-07T10:42:54', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '9dd5c0e5-31d7-445a-b3ab-78388c99e952'	System	11 Sep 2020 18:11:28
User entered '07 Sep 2020 10:42'	System	11 Sep 2020 18:11:28

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered 'Day 4'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered 'Day 5'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-08T14:46:03', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'cc9ab299-74be-46a0-a416-a4829f5e05a3' User entered 'None (1)'	System	11 Sep 2020 18:11:28
	System	11 Sep 2020 18:11:28

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-08T14:46:07', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'cc9ab299-74be-46a0-a416-a4829f5e05a3' User entered 'No (N)'	System	11 Sep 2020 18:11:28
	System	11 Sep 2020 18:11:28

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-08T14:46:10', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'cc9ab299-74be-46a0-a416-a4829f5e05a3' User entered 'No (N)'	System	11 Sep 2020 18:11:28
	System	11 Sep 2020 18:11:28

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-08T14:46:14', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'cc9ab299-74be-46a0-a416-a4829f5e05a3' User entered 'None (1)'	System	11 Sep 2020 18:11:28
	System	11 Sep 2020 18:11:28

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-08T14:46:16', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'cc9ab299-74be-46a0-a416-a4829f5e05a3' User entered '08 Sep 2020 14:46'	System	11 Sep 2020 18:11:28
	System	11 Sep 2020 18:11:28

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered 'Day 6'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-09T13:28:46', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '0503dcf1-ca03-44bd-9730-c6844674ee08'	System	11 Sep 2020 18:11:39
User entered 'None (1)'	System	11 Sep 2020 18:11:39

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-09T13:28:50', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '0503dcf1-ca03-44bd-9730-c6844674ee08' User entered 'No (N)'	System	11 Sep 2020 18:11:39
	System	11 Sep 2020 18:11:39

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-09T13:28:54', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '0503dcf1-ca03-44bd-9730-c6844674ee08'	System	11 Sep 2020 18:11:39
User entered 'No (N)'	System	11 Sep 2020 18:11:39

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-09T13:28:58', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '0503dcf1-ca03-44bd-9730-c6844674ee08' User entered 'None (1)'	System	11 Sep 2020 18:11:39
	System	11 Sep 2020 18:11:39

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-09T13:29:01', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '0503dcf1-ca03-44bd-9730-c6844674ee08' User entered '09 Sep 2020 13:29'	System	11 Sep 2020 18:11:39
	System	11 Sep 2020 18:11:39

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered 'Day 7'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-10T14:40:09', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'd22492ef-a78f-4fa7-a00d-979b2358560d' User entered 'None (1)'	System	11 Sep 2020 18:11:43
	System	11 Sep 2020 18:11:43

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:23:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-10T14:40:13', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'd22492ef-a78f-4fa7-a00d-979b2358560d' User entered 'No (N)'	System	11 Sep 2020 18:11:43
	System	11 Sep 2020 18:11:43

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-10T14:40:16', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'd22492ef-a78f-4fa7-a00d-979b2358560d' User entered 'No (N)'	System	11 Sep 2020 18:11:43
	System	11 Sep 2020 18:11:43

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-10T14:40:18', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'd22492ef-a78f-4fa7-a00d-979b2358560d' User entered 'None (1)'	System	11 Sep 2020 18:11:43
	System	11 Sep 2020 18:11:43

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-10T14:40:48', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'd22492ef-a78f-4fa7-a00d-979b2358560d' User entered '10 Sep 2020 14:40'	System	11 Sep 2020 18:11:43
	System	11 Sep 2020 18:11:43

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-04T14:53:06', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '248a9dce-ce63-4792-8a14-cb4ad04fe7c4' User entered 'None (0)'	System	04 Sep 2020 20:53:41
	System	04 Sep 2020 20:53:41

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-04T14:53:10', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '248a9dce-ce63-4792-8a14-cb4ad04fe7c4' User entered 'None (0)'	System	04 Sep 2020 20:53:41
	System	04 Sep 2020 20:53:41

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-04T14:53:14', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '248a9dce-ce63-4792-8a14-cb4ad04fe7c4' User entered 'None (0)'	System	04 Sep 2020 20:53:41
	System	04 Sep 2020 20:53:41

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-04T14:53:17', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '248a9dce-ce63-4792-8a14-cb4ad04fe7c4' User entered 'None (0)'	System	04 Sep 2020 20:53:41
	System	04 Sep 2020 20:53:41

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-04T14:53:27', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '248a9dce-ce63-4792-8a14-cb4ad04fe7c4' User entered 'None (0)'	System	04 Sep 2020 20:53:41
	System	04 Sep 2020 20:53:41

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-04T14:53:29', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '248a9dce-ce63-4792-8a14-cb4ad04fe7c4' User entered 'None (0)'	System	04 Sep 2020 20:53:41
	System	04 Sep 2020 20:53:41

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-04T14:53:35', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '248a9dce-ce63-4792-8a14-cb4ad04fe7c4' User entered 'No (N)'	System	04 Sep 2020 20:53:41
	System	04 Sep 2020 20:53:41

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-04T14:53:38', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '248a9dce-ce63-4792-8a14-cb4ad04fe7c4' User entered '04 Sep 2020 14:53'	System	04 Sep 2020 20:53:41
	System	04 Sep 2020 20:53:41

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '04 Sep 2020 14:38'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '04 Sep 2020 17:08'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-05T11:43:49', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '42f87b7b-07aa-4b30-bf91-fb2074a3b9d5' User entered 'None (0)'	System	11 Sep 2020 18:10:18
	System	11 Sep 2020 18:10:18

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-05T11:43:53', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '42f87b7b-07aa-4b30-bf91-fb2074a3b9d5' User entered 'None (0)'	System	11 Sep 2020 18:10:18
	System	11 Sep 2020 18:10:18

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-05T11:43:56', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '42f87b7b-07aa-4b30-bf91-fb2074a3b9d5' User entered 'None (0)'	System	11 Sep 2020 18:10:18
	System	11 Sep 2020 18:10:18

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-05T11:43:59', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '42f87b7b-07aa-4b30-bf91-fb2074a3b9d5' User entered 'None (0)'	System	11 Sep 2020 18:10:18
	System	11 Sep 2020 18:10:18

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-05T11:44:02', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '42f87b7b-07aa-4b30-bf91-fb2074a3b9d5' User entered 'None (0)'	System	11 Sep 2020 18:10:18
	System	11 Sep 2020 18:10:18

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-05T11:44:04', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '42f87b7b-07aa-4b30-bf91-fb2074a3b9d5' User entered 'None (0)'	System	11 Sep 2020 18:10:18
	System	11 Sep 2020 18:10:18

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-05T11:44:08', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '42f87b7b-07aa-4b30-bf91-fb2074a3b9d5' User entered 'No (N)'	System	11 Sep 2020 18:10:18
	System	11 Sep 2020 18:10:18

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-05T11:44:12', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '42f87b7b-07aa-4b30-bf91-fb2074a3b9d5' User entered '05 Sep 2020 11:44'	System	11 Sep 2020 18:10:18
	System	11 Sep 2020 18:10:18

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '04 Sep 2020 18:03'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered 'Day 2'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-06T10:59:40', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '6dcfdd7d-c0de-4afc-8a25-6418c0f67594' User entered 'None (0)'	System	11 Sep 2020 18:11:16
	System	11 Sep 2020 18:11:16

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-06T10:59:43', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '6dcfdd7d-c0de-4afc-8a25-6418c0f67594' User entered 'None (0)'	System	11 Sep 2020 18:11:16
	System	11 Sep 2020 18:11:16

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-06T10:59:45', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '6dcfdd7d-c0de-4afc-8a25-6418c0f67594' User entered 'None (0)'	System	11 Sep 2020 18:11:16
	System	11 Sep 2020 18:11:16

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-06T10:59:48', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '6dcfdd7d-c0de-4afc-8a25-6418c0f67594' User entered 'None (0)'	System	11 Sep 2020 18:11:16
	System	11 Sep 2020 18:11:16

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-06T10:59:50', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '6dcfdd7d-c0de-4afc-8a25-6418c0f67594' User entered 'None (0)'	System	11 Sep 2020 18:11:16
	System	11 Sep 2020 18:11:16

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-06T10:59:52', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '6dcfdd7d-c0de-4afc-8a25-6418c0f67594' User entered 'None (0)'	System	11 Sep 2020 18:11:16
	System	11 Sep 2020 18:11:16

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-06T10:59:55', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '6dcfdd7d-c0de-4afc-8a25-6418c0f67594' User entered 'No (N)'	System	11 Sep 2020 18:11:16
	System	11 Sep 2020 18:11:16

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-06T10:59:58', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '6dcfdd7d-c0de-4afc-8a25-6418c0f67594' User entered '06 Sep 2020 10:59'	System	11 Sep 2020 18:11:16
	System	11 Sep 2020 18:11:16

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered 'Day 3'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-07T10:42:58', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'ece157a3-abfc-4a23-ace3-008168f40b84' User entered 'None (0)'	System	11 Sep 2020 18:11:28
	System	11 Sep 2020 18:11:28

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-07T10:43:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'ece157a3-abfc-4a23-ace3-008168f40b84' User entered 'None (0)'	System	11 Sep 2020 18:11:28
	System	11 Sep 2020 18:11:28

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-07T10:43:03', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'ece157a3-abfc-4a23-ace3-008168f40b84' User entered 'None (0)'	System	11 Sep 2020 18:11:28
	System	11 Sep 2020 18:11:28

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-07T10:43:05', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'ece157a3-abfc-4a23-ace3-008168f40b84' User entered 'None (0)'	System	11 Sep 2020 18:11:28
	System	11 Sep 2020 18:11:28

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-07T10:43:07', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'ece157a3-abfc-4a23-ace3-008168f40b84' User entered 'None (0)'	System	11 Sep 2020 18:11:28
	System	11 Sep 2020 18:11:28

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-07T10:43:09', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'ece157a3-abfc-4a23-ace3-008168f40b84' User entered 'None (0)'	System	11 Sep 2020 18:11:28
	System	11 Sep 2020 18:11:28

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-07T10:43:11', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'ece157a3-abfc-4a23-ace3-008168f40b84' User entered 'No (N)'	System	11 Sep 2020 18:11:28
	System	11 Sep 2020 18:11:28

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-07T10:43:14', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'ece157a3-abfc-4a23-ace3-008168f40b84' User entered '07 Sep 2020 10:43'	System	11 Sep 2020 18:11:28
	System	11 Sep 2020 18:11:28

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered 'Day 4'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered 'Day 5'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-08T14:46:21', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '0d089648-c414-44c7-b510-5637ed34e838' User entered 'None (0)'	System	11 Sep 2020 18:11:34
	System	11 Sep 2020 18:11:34

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-08T14:46:23', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '0d089648-c414-44c7-b510-5637ed34e838'	System	11 Sep 2020 18:11:34
User entered 'None (0)'	System	11 Sep 2020 18:11:34

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-08T14:46:25', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '0d089648-c414-44c7-b510-5637ed34e838' User entered 'None (0)'	System	11 Sep 2020 18:11:34
	System	11 Sep 2020 18:11:34

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-08T14:46:27', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '0d089648-c414-44c7-b510-5637ed34e838' User entered 'None (0)'	System	11 Sep 2020 18:11:34
	System	11 Sep 2020 18:11:34

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-08T14:46:29', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '0d089648-c414-44c7-b510-5637ed34e838' User entered 'None (0)'	System	11 Sep 2020 18:11:34
	System	11 Sep 2020 18:11:34

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-08T14:46:31', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '0d089648-c414-44c7-b510-5637ed34e838' User entered 'None (0)'	System	11 Sep 2020 18:11:34
	System	11 Sep 2020 18:11:34

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-08T14:46:33', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '0d089648-c414-44c7-b510-5637ed34e838'	System	11 Sep 2020 18:11:34
User entered 'No (N)'	System	11 Sep 2020 18:11:34

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-08T14:46:35', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '0d089648-c414-44c7-b510-5637ed34e838' User entered '08 Sep 2020 14:46'	System	11 Sep 2020 18:11:34
	System	11 Sep 2020 18:11:34

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered 'Day 6'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-09T13:29:06', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '4947eb48-c56c-496c-8e90-32dc5a00fe62' User entered 'None (0)'	System	11 Sep 2020 18:11:39
	System	11 Sep 2020 18:11:39

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-09T13:29:09', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '4947eb48-c56c-496c-8e90-32dc5a00fe62' User entered 'None (0)'	System	11 Sep 2020 18:11:39
	System	11 Sep 2020 18:11:39

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-09T13:29:12', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '4947eb48-c56c-496c-8e90-32dc5a00fe62' User entered 'None (0)'	System	11 Sep 2020 18:11:39
	System	11 Sep 2020 18:11:39

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-09T13:29:15', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '4947eb48-c56c-496c-8e90-32dc5a00fe62' User entered 'None (0)'	System	11 Sep 2020 18:11:39
	System	11 Sep 2020 18:11:39

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-09T13:29:18', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '4947eb48-c56c-496c-8e90-32dc5a00fe62' User entered 'None (0)'	System	11 Sep 2020 18:11:39
	System	11 Sep 2020 18:11:39

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-09T13:29:21', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '4947eb48-c56c-496c-8e90-32dc5a00fe62' User entered 'None (0)'	System	11 Sep 2020 18:11:39
	System	11 Sep 2020 18:11:39

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-09T13:29:25', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '4947eb48-c56c-496c-8e90-32dc5a00fe62' User entered 'No (N)'	System	11 Sep 2020 18:11:39
	System	11 Sep 2020 18:11:39

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-09T13:29:27', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '4947eb48-c56c-496c-8e90-32dc5a00fe62' User entered '09 Sep 2020 13:29'	System	11 Sep 2020 18:11:39
	System	11 Sep 2020 18:11:39

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered 'Day 7'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-10T14:40:53', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'd64a851d-6a96-494f-9a63-8030c3407f01' User entered 'None (0)'	System	11 Sep 2020 18:11:44
	System	11 Sep 2020 18:11:44

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-10T14:40:56', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'd64a851d-6a96-494f-9a63-8030c3407f01' User entered 'None (0)'	System	11 Sep 2020 18:11:44
	System	11 Sep 2020 18:11:44

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-10T14:40:59', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'd64a851d-6a96-494f-9a63-8030c3407f01' User entered 'None (0)'	System	11 Sep 2020 18:11:44
	System	11 Sep 2020 18:11:44

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-10T14:41:20', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'd64a851d-6a96-494f-9a63-8030c3407f01' User entered 'None (0)'	System	11 Sep 2020 18:11:44
	System	11 Sep 2020 18:11:44

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-10T14:41:25', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'd64a851d-6a96-494f-9a63-8030c3407f01' User entered 'None (0)'	System	11 Sep 2020 18:11:44
	System	11 Sep 2020 18:11:44

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-10T14:41:28', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'd64a851d-6a96-494f-9a63-8030c3407f01' User entered 'None (0)'	System	11 Sep 2020 18:11:44
	System	11 Sep 2020 18:11:44

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-10T14:41:33', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'd64a851d-6a96-494f-9a63-8030c3407f01' User entered 'No (N)'	System	11 Sep 2020 18:11:44
	System	11 Sep 2020 18:11:44

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (145DCA64-EF94-4267-BEEE-EA979F5A28D8)', Time: '2020-09-10T14:41:36', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'd64a851d-6a96-494f-9a63-8030c3407f01' User entered '10 Sep 2020 14:41'	System	11 Sep 2020 18:11:44
	System	11 Sep 2020 18:11:44

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 20:29:05

US3892054

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 20:29:05

US3892054

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	11 Sep 2020 23:01:58

US3892054

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered '11 Sep 2020'	(b) (4) Stefanie Vasconez (b) (4)	11 Sep 2020 23:01:58

US3892054

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stefanie Vasconez (b) (4)	11 Sep 2020 23:01:58

US3892054

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered empty.	(b) (4) Stefanie Vasconez (b) (4)	11 Sep 2020 23:01:58

US3892054

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	11 Sep 2020 23:02:03

US3892054

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'I'	System	11 Sep 2020 23:02:03

US3892054

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	18 Sep 2020 19:37:06

US3892054

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered '18 Sep 2020'	(b) (4) Stefanie Vasconez (b) (4)	18 Sep 2020 19:37:06

US3892054

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stefanie Vasconez (b) (4)	18 Sep 2020 19:37:06

US3892054

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered empty.	(b) (4) Stefanie Vasconez (b) (4)	18 Sep 2020 19:37:06

US3892054

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	18 Sep 2020 19:38:25

US3892054

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'I'	System	18 Sep 2020 19:38:25

US3892054

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	25 Sep 2020 18:35:15

US3892054

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered '25 Sep 2020'	(b) (4) Stefanie Vasconez (b) (4)	25 Sep 2020 18:35:15

US3892054

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stefanie Vasconez (b) (4)	25 Sep 2020 18:35:15

US3892054

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered empty.	Stefanie Vasconez (b) (4)	25 Sep 2020 18:35:15

US3892054

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	25 Sep 2020 18:35:20

US3892054

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'I'	System	25 Sep 2020 18:35:20

US3892054

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:23:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 19:56:45

US3892054

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '02 Oct 2020'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 19:56:45

US3892054

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Clinic (Clinic)'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 19:56:45

US3892054

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:23:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'VISIT2'	System	02 Oct 2020 19:56:45

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User accepted default value 'Pre-Dose (PREDOSE)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:48:25
	(b) (4)	

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '02 Oct 2020'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '11:55'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '02 Oct 2020 11:55'	System	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '98.3' F	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Oral (Oral)'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

Pulse (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User closed query 'Per CDM: Per CCG V2.0 page 53, PULSE \leq 54 or \geq 101 beats per minute (beats/min) is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 06:34:04
Query 'Per CDM: Per CCG V2.0 page 53, PULSE \leq 54 or \geq 101 beats per minute (beats/min) is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' answered with 'Per PA; NCS' (Site from DM).	Andryelle Toledo (b) (4)	05 Jan 2021 02:34:37
User opened query 'Per CDM: Per CCG V2.0 page 53, PULSE \leq 54 or \geq 101 beats per minute (beats/min) is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Dec 2020 17:35:28
User entered '109'	Andryelle Toledo (b) (4)	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'bpm'	System	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '12'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'breaths/min'	System	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '139'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'mmHg'	System	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User closed query 'Per CDM: Per CCG V2.0 page 53, Diastolic Blood Pressure \geq 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 06:34:08
Query 'Per CDM: Per CCG V2.0 page 53, Diastolic Blood Pressure \geq 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' answered with 'Per PA; NCS' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	05 Jan 2021 02:34:41
User opened query 'Per CDM: Per CCG V2.0 page 53, Diastolic Blood Pressure \geq 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 07:44:23
User entered '97'	Andryelle Toledo (b) (4) (b) (4)	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'mmHg'	System	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User accepted default value 'Post-Dose (POSTDOSE)'	Andryelle Toledo (b) (4) (b) (4)	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '02 Oct 2020'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '14:09'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '02 Oct 2020 14:09'	System	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '98.0' F	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Oral (Oral)'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '97'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'bpm'	System	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '12'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'breaths/min'	System	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '119'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'mmHg'	System	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '82'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'mmHg'	System	02 Oct 2020 21:48:25

US3892054

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:23:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 21:48:55

US3892054

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:23:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '02 Oct 2020'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 21:48:55

US3892054

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:23:48

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	12 Oct 2020 22:19:02

US3892054

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:23:48

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '02 Oct 2020'	(b) (4) Andryelle Toledo (b) (4)	12 Oct 2020 22:19:02

US3892054

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:23:48

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Urine (URINE)'	(b) (4) Andryelle Toledo (b) (4)	12 Oct 2020 22:19:02

US3892054

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:23:48

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Negative (NEGATIVE)'	(b) (4) Andryelle Toledo (b) (4)	12 Oct 2020 22:19:02

US3892054

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:23:48

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	12 Oct 2020 22:19:02

US3892054

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:23:48

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	12 Oct 2020 22:19:02

US3892054

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:23:48

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	12 Oct 2020 22:19:02

US3892054

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered empty.	System	12 Oct 2020 22:19:02

US3892054

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:23:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 19:57:08

US3892054

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:23:48

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 19:57:08

US3892054

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 19:57:08

US3892054

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:23:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'MRNA-1273 OR PLACEBO'	System	02 Oct 2020 19:57:08

US3892054

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:23:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '02 Oct 2020'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 19:57:08

US3892054

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '13:37'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 19:57:08

US3892054

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '02 Oct 2020 13:37'	System	02 Oct 2020 19:57:08

US3892054

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:23:48

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4)	02 Oct 2020 22:10:19
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	02 Oct 2020 22:10:19
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	02 Oct 2020 19:57:08
User entered 'Left Arm (LEFT ARM)'	Andryelle Toledo (b) (4)	02 Oct 2020 19:57:08
	(b) (4)	

US3892054

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:23:48

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'ONCE'	System	02 Oct 2020 19:57:08

US3892054

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:23:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'INTRAMUSCULAR'	System	02 Oct 2020 19:57:08

US3892054

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 21:49:46

US3892054

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '02 Oct 2020'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 21:49:46

US3892054

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:48

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '12:57'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 21:49:46

US3892054

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '02 Oct 2020 12:57'	System	02 Oct 2020 21:49:46

US3892054

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:23:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '02 Oct 2020'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 21:50:17

US3892054

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:23:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:50:17

US3892054

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:23:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	13 Oct 2020 18:31:23
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:50:17
	(b) (4)	

US3892054

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:23:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '12:16' reason for change: Data Entry Error	(b) (4)	13 Oct 2020 18:31:23
User entered empty.	Andryelle Toledo (b) (4)	02 Oct 2020 21:50:17
	(b) (4)	

US3892054

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '02 Oct 2020 12:16'	System	13 Oct 2020 18:31:23
User entered empty.	System	02 Oct 2020 21:50:17

US3892054

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:23:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:50:17

US3892054

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:23:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	13 Oct 2020 18:31:23
User entered 'Yes (Y)'	(b) (4)	
	Andryelle Toledo (b) (4)	02 Oct 2020 21:50:17
	(b) (4)	

US3892054

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:23:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty; reason for change Data Entry Error	(b) (4)	13 Oct 2020 18:31:23
User entered '12:16'	Andryelle Toledo (b) (4)	02 Oct 2020 21:50:17
	(b) (4)	

US3892054

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered empty.	System	13 Oct 2020 18:31:23
User entered '02 Oct 2020 12:16'	System	02 Oct 2020 21:50:17

US3892054

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	02 Oct 2020 21:50:23

US3892054

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'I'	System	02 Oct 2020 21:50:23

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	02 Oct 2020 19:57:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-02T14:12:03', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '2454caca-1d45-4e69-aaeb-6f5c18b41577'	System	02 Oct 2020 20:12:20
User entered 'Yes (Y)'	System	02 Oct 2020 20:12:20

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-02T14:12:10', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '2454caca-1d45-4e69-aaeb-6f5c18b41577' User entered '98.0'	System	02 Oct 2020 20:12:20
	System	02 Oct 2020 20:12:20

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-02T14:12:14', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '2454caca-1d45-4e69-aaeb-6f5c18b41577'	System	02 Oct 2020 20:12:20
User entered 'No (N)'	System	02 Oct 2020 20:12:20

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-02T14:12:18', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '2454caca-1d45-4e69-aaeb-6f5c18b41577'	System	02 Oct 2020 20:12:20
User entered '02 Oct 2020 14:12'	System	02 Oct 2020 20:12:20

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '02 Oct 2020 13:57'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '02 Oct 2020 16:27'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	02 Oct 2020 19:57:08
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T06:55:03', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '3dac1070-e04c-44ca-a124-f45f0df2d189' User entered 'Yes (Y)'	System	03 Oct 2020 12:55:23
	System	03 Oct 2020 12:55:23

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T06:55:09', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '3dac1070-e04c-44ca-a124-f45f0df2d189' User entered '97.2'	System	03 Oct 2020 12:55:23
	System	03 Oct 2020 12:55:23

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T06:55:14', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '3dac1070-e04c-44ca-a124-f45f0df2d189' User entered 'No (N)'	System	03 Oct 2020 12:55:23
	System	03 Oct 2020 12:55:23

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T06:55:18', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '3dac1070-e04c-44ca-a124-f45f0df2d189' User entered '03 Oct 2020 06:55'	System	03 Oct 2020 12:55:23
	System	03 Oct 2020 12:55:23

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '02 Oct 2020 17:22'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	02 Oct 2020 19:57:08
User entered 'Day 2'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:23:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T15:00:12', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '93907ca3-dc6a-4b5f-a657-d83a737fb189'	System	03 Oct 2020 21:01:12
User entered 'Yes (Y)'	System	03 Oct 2020 21:01:12

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:23:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T15:00:17', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '93907ca3-dc6a-4b5f-a657-d83a737fb189' User entered '97.9'	System	03 Oct 2020 21:01:12
	System	03 Oct 2020 21:01:12

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T15:00:20', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '93907ca3-dc6a-4b5f-a657-d83a737fb189'	System	03 Oct 2020 21:01:12
User entered 'No (N)'	System	03 Oct 2020 21:01:12

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T15:00:24', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '93907ca3-dc6a-4b5f-a657-d83a737fb189' User entered '03 Oct 2020 15:00'	System	03 Oct 2020 21:01:12
	System	03 Oct 2020 21:01:12

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	02 Oct 2020 19:57:08
User entered 'Day 3'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:23:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-04T16:12:16', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'ea1895a1-38f4-4c79-be95-4adc8e3aa3fc' User entered 'Yes (Y)'	System	04 Oct 2020 22:12:33
	System	04 Oct 2020 22:12:33

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:23:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-04T16:12:21', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'ea1895a1-38f4-4c79-be95-4adc8e3aa3fc' User entered '98.2'	System	04 Oct 2020 22:12:33
	System	04 Oct 2020 22:12:33

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-04T16:12:24', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'ea1895a1-38f4-4c79-be95-4adc8e3aa3fc'	System	04 Oct 2020 22:12:33
User entered 'No (N)'	System	04 Oct 2020 22:12:33

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-04T16:12:27', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'ea1895a1-38f4-4c79-be95-4adc8e3aa3fc' User entered '04 Oct 2020 16:12'	System	04 Oct 2020 22:12:33
	System	04 Oct 2020 22:12:33

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	02 Oct 2020 19:57:08
User entered 'Day 4'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:23:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:23:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:23:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	02 Oct 2020 19:57:08
User entered 'Day 5'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:23:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:23:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:23:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	02 Oct 2020 19:57:08
User entered 'Day 6'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:23:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:23:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:23:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	02 Oct 2020 19:57:08
User entered 'Day 7'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:23:48

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-08T21:24:12', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'd7869d5f-0b88-49c3-9fdf-0d90ebfd0bfd' User entered 'Yes (Y)'	System	09 Oct 2020 03:24:26
	System	09 Oct 2020 03:24:26

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:23:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-08T21:24:17', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'd7869d5f-0b88-49c3-9fdf-0d90ebfd0bfd' User entered '98.2'	System	09 Oct 2020 03:24:26
	System	09 Oct 2020 03:24:26

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-08T21:24:20', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'd7869d5f-0b88-49c3-9fdf-0d90ebfd0bfd'	System	09 Oct 2020 03:24:26
User entered 'No (N)'	System	09 Oct 2020 03:24:26

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-08T21:24:23', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'd7869d5f-0b88-49c3-9fdf-0d90ebfd0bfd' User entered '08 Oct 2020 21:24'	System	09 Oct 2020 03:24:26
	System	09 Oct 2020 03:24:26

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	02 Oct 2020 19:57:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-02T14:12:24', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'b3dc50fe-d621-4466-9344-791b01e94736'	System	02 Oct 2020 20:12:46
User entered 'None (1)'	System	02 Oct 2020 20:12:46

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-02T14:12:29', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'b3dc50fe-d621-4466-9344-791b01e94736'	System	02 Oct 2020 20:12:46
User entered 'No (N)'	System	02 Oct 2020 20:12:46

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-02T14:12:34', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'b3dc50fe-d621-4466-9344-791b01e94736' User entered 'No (N)'	System	02 Oct 2020 20:12:46
	System	02 Oct 2020 20:12:46

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-02T14:12:41', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'b3dc50fe-d621-4466-9344-791b01e94736'	System	02 Oct 2020 20:12:46
User entered 'None (1)'	System	02 Oct 2020 20:12:46

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-02T14:12:44', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'b3dc50fe-d621-4466-9344-791b01e94736' User entered '02 Oct 2020 14:12'	System	02 Oct 2020 20:12:46
	System	02 Oct 2020 20:12:46

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '02 Oct 2020 13:57'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '02 Oct 2020 16:27'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	02 Oct 2020 19:57:08
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T06:55:30', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '782e4868-f1dd-4f6f-bdf5-8ee8d69aa1f3'	System	03 Oct 2020 12:55:46
User entered 'Does not interfere with activity (2)'	System	03 Oct 2020 12:55:46

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T06:55:33', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '782e4868-f1dd-4f6f-bdf5-8ee8d69aa1f3'	System	03 Oct 2020 12:55:46
User entered 'No (N)'	System	03 Oct 2020 12:55:46

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T06:55:36', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '782e4868-f1dd-4f6f-bdf5-8ee8d69aa1f3'	System	03 Oct 2020 12:55:46
User entered 'No (N)'	System	03 Oct 2020 12:55:46

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T06:55:40', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '782e4868-f1dd-4f6f-bdf5-8ee8d69aa1f3'	System	03 Oct 2020 12:55:46
User entered 'None (1)'	System	03 Oct 2020 12:55:46

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T06:55:43', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '782e4868-f1dd-4f6f-bdf5-8ee8d69aa1f3'	System	03 Oct 2020 12:55:46
User entered '03 Oct 2020 06:55'	System	03 Oct 2020 12:55:46

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '02 Oct 2020 17:22'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	02 Oct 2020 19:57:08
User entered 'Day 2'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T15:00:40', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'b6fe2b14-6282-4c39-a7d9-0a992cc0126c'	System	03 Oct 2020 21:01:38
User entered 'Does not interfere with activity (2)'	System	03 Oct 2020 21:01:38

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T15:00:43', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'b6fe2b14-6282-4c39-a7d9-0a992cc0126c' User entered 'No (N)'	System	03 Oct 2020 21:01:38
	System	03 Oct 2020 21:01:38

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T15:01:02', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'b6fe2b14-6282-4c39-a7d9-0a992cc0126c' User entered 'Yes (Y)'	System	03 Oct 2020 21:01:38
	System	03 Oct 2020 21:01:38

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T15:01:13', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'b6fe2b14-6282-4c39-a7d9-0a992cc0126c' User entered '2'	System	03 Oct 2020 21:01:38
	System	03 Oct 2020 21:01:38

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T15:01:26', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'b6fe2b14-6282-4c39-a7d9-0a992cc0126c' User entered 'None (1)'	System	03 Oct 2020 21:01:38
	System	03 Oct 2020 21:01:38

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T15:01:29', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'b6fe2b14-6282-4c39-a7d9-0a992cc0126c' User entered '03 Oct 2020 15:01'	System	03 Oct 2020 21:01:38
	System	03 Oct 2020 21:01:38

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	02 Oct 2020 19:57:08
User entered 'Day 3'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-04T16:12:32', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '20c3024e-fa87-43c5-b4a1-7af34700e98d'	System	04 Oct 2020 22:12:44
User entered 'None (1)'	System	04 Oct 2020 22:12:44

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:23:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-04T16:12:34', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '20c3024e-fa87-43c5-b4a1-7af34700e98d' User entered 'No (N)'	System	04 Oct 2020 22:12:44
	System	04 Oct 2020 22:12:44

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-04T16:12:37', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '20c3024e-fa87-43c5-b4a1-7af34700e98d' User entered 'No (N)'	System	04 Oct 2020 22:12:44
	System	04 Oct 2020 22:12:44

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-04T16:12:39', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '20c3024e-fa87-43c5-b4a1-7af34700e98d'	System	04 Oct 2020 22:12:44
User entered 'None (1)'	System	04 Oct 2020 22:12:44

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-04T16:12:42', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '20c3024e-fa87-43c5-b4a1-7af34700e98d' User entered '04 Oct 2020 16:12'	System	04 Oct 2020 22:12:44
	System	04 Oct 2020 22:12:44

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	02 Oct 2020 19:57:08
User entered 'Day 4'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	02 Oct 2020 19:57:08
User entered 'Day 5'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	02 Oct 2020 19:57:08
User entered 'Day 6'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	02 Oct 2020 19:57:08
User entered 'Day 7'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-08T21:24:28', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '38881baa-4a32-40ac-bbf6-9440eb9168f2' User entered 'None (1)'	System	09 Oct 2020 03:24:58
	System	09 Oct 2020 03:24:58

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:23:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-08T21:24:31', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '38881baa-4a32-40ac-bbf6-9440eb9168f2' User entered 'No (N)'	System	09 Oct 2020 03:24:58
	System	09 Oct 2020 03:24:58

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-08T21:24:34', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '38881baa-4a32-40ac-bbf6-9440eb9168f2' User entered 'No (N)'	System	09 Oct 2020 03:24:58
	System	09 Oct 2020 03:24:58

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-08T21:24:54', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '38881baa-4a32-40ac-bbf6-9440eb9168f2' User entered 'None (1)'	System	09 Oct 2020 03:24:58
	System	09 Oct 2020 03:24:58

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:23:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-08T21:24:57', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '38881baa-4a32-40ac-bbf6-9440eb9168f2' User entered '08 Oct 2020 21:24'	System	09 Oct 2020 03:24:58
	System	09 Oct 2020 03:24:58

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	02 Oct 2020 19:57:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-02T14:12:48', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'fc249a7c-670d-48b8-b3fc-25573d15620a' User entered 'None (0)'	System	02 Oct 2020 20:13:14
	System	02 Oct 2020 20:13:14

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-02T14:12:50', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'fc249a7c-670d-48b8-b3fc-25573d15620a' User entered 'None (0)'	System	02 Oct 2020 20:13:14
	System	02 Oct 2020 20:13:14

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-02T14:12:55', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'fc249a7c-670d-48b8-b3fc-25573d15620a' User entered 'None (0)'	System	02 Oct 2020 20:13:14
	System	02 Oct 2020 20:13:14

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-02T14:12:59', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'fc249a7c-670d-48b8-b3fc-25573d15620a' User entered 'None (0)'	System	02 Oct 2020 20:13:14
	System	02 Oct 2020 20:13:14

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-02T14:13:02', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'fc249a7c-670d-48b8-b3fc-25573d15620a' User entered 'None (0)'	System	02 Oct 2020 20:13:14
	System	02 Oct 2020 20:13:14

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-02T14:13:04', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'fc249a7c-670d-48b8-b3fc-25573d15620a' User entered 'None (0)'	System	02 Oct 2020 20:13:14
	System	02 Oct 2020 20:13:14

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-02T14:13:08', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'fc249a7c-670d-48b8-b3fc-25573d15620a' User entered 'No (N)'	System	02 Oct 2020 20:13:14
	System	02 Oct 2020 20:13:14

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-02T14:13:11', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'fc249a7c-670d-48b8-b3fc-25573d15620a' User entered '02 Oct 2020 14:13'	System	02 Oct 2020 20:13:14
	System	02 Oct 2020 20:13:14

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '02 Oct 2020 13:57'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '02 Oct 2020 16:27'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	02 Oct 2020 19:57:08
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T06:55:48', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '03407794-d79e-4052-99b3-f1d4d7a49e66' User entered 'None (0)'	System	03 Oct 2020 12:56:10
	System	03 Oct 2020 12:56:10

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T06:55:50', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '03407794-d79e-4052-99b3-f1d4d7a49e66' User entered 'None (0)'	System	03 Oct 2020 12:56:10
	System	03 Oct 2020 12:56:10

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T06:55:54', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '03407794-d79e-4052-99b3-f1d4d7a49e66' User entered 'None (0)'	System	03 Oct 2020 12:56:10
	System	03 Oct 2020 12:56:10

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T06:55:57', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '03407794-d79e-4052-99b3-f1d4d7a49e66' User entered 'None (0)'	System	03 Oct 2020 12:56:10
	System	03 Oct 2020 12:56:10

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T06:55:59', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '03407794-d79e-4052-99b3-f1d4d7a49e66' User entered 'None (0)'	System	03 Oct 2020 12:56:10
	System	03 Oct 2020 12:56:10

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T06:56:02', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '03407794-d79e-4052-99b3-f1d4d7a49e66' User entered 'None (0)'	System	03 Oct 2020 12:56:10
	System	03 Oct 2020 12:56:10

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T06:56:05', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '03407794-d79e-4052-99b3-f1d4d7a49e66' User entered 'No (N)'	System	03 Oct 2020 12:56:10
	System	03 Oct 2020 12:56:10

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T06:56:08', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '03407794-d79e-4052-99b3-f1d4d7a49e66' User entered '03 Oct 2020 06:56'	System	03 Oct 2020 12:56:10
	System	03 Oct 2020 12:56:10

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '02 Oct 2020 17:22'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	02 Oct 2020 19:57:08
User entered 'Day 2'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T15:01:33', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '319be9f4-711c-4385-889a-52a17793ee6f' User entered 'None (0)'	System	03 Oct 2020 21:01:52
	System	03 Oct 2020 21:01:52

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T15:01:35', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '319be9f4-711c-4385-889a-52a17793ee6f' User entered 'None (0)'	System	03 Oct 2020 21:01:52
	System	03 Oct 2020 21:01:52

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T15:01:38', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '319be9f4-711c-4385-889a-52a17793ee6f' User entered 'None (0)'	System	03 Oct 2020 21:01:52
	System	03 Oct 2020 21:01:52

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T15:01:40', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '319be9f4-711c-4385-889a-52a17793ee6f' User entered 'None (0)'	System	03 Oct 2020 21:01:52
	System	03 Oct 2020 21:01:52

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T15:01:43', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '319be9f4-711c-4385-889a-52a17793ee6f' User entered 'None (0)'	System	03 Oct 2020 21:01:52
	System	03 Oct 2020 21:01:52

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T15:01:45', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '319be9f4-711c-4385-889a-52a17793ee6f' User entered 'None (0)'	System	03 Oct 2020 21:01:52
	System	03 Oct 2020 21:01:52

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T15:01:48', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '319be9f4-711c-4385-889a-52a17793ee6f' User entered 'No (N)'	System	03 Oct 2020 21:01:52
	System	03 Oct 2020 21:01:52

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-03T15:01:50', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '319be9f4-711c-4385-889a-52a17793ee6f' User entered '03 Oct 2020 15:01'	System	03 Oct 2020 21:01:52
	System	03 Oct 2020 21:01:52

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	02 Oct 2020 19:57:08
User entered 'Day 3'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-04T16:12:49', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'cb341777-08d5-4fc9-8f11-b4aaff7450d4' User entered 'None (0)'	System	04 Oct 2020 22:13:15
	System	04 Oct 2020 22:13:15

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-04T16:12:51', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'cb341777-08d5-4fc9-8f11-b4aaff7450d4' User entered 'None (0)'	System	04 Oct 2020 22:13:15
	System	04 Oct 2020 22:13:15

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-04T16:12:53', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'cb341777-08d5-4fc9-8f11-b4aaff7450d4' User entered 'None (0)'	System	04 Oct 2020 22:13:15
	System	04 Oct 2020 22:13:15

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-04T16:12:55', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'cb341777-08d5-4fc9-8f11-b4aaff7450d4' User entered 'None (0)'	System	04 Oct 2020 22:13:15
	System	04 Oct 2020 22:13:15

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-04T16:12:57', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'cb341777-08d5-4fc9-8f11-b4aaff7450d4' User entered 'None (0)'	System	04 Oct 2020 22:13:15
	System	04 Oct 2020 22:13:15

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-04T16:12:59', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'cb341777-08d5-4fc9-8f11-b4aaff7450d4' User entered 'None (0)'	System	04 Oct 2020 22:13:15
	System	04 Oct 2020 22:13:15

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-04T16:13:10', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'cb341777-08d5-4fc9-8f11-b4aaff7450d4'	System	04 Oct 2020 22:13:15
User entered 'No (N)'	System	04 Oct 2020 22:13:15

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-04T16:13:12', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'cb341777-08d5-4fc9-8f11-b4aaff7450d4' User entered '04 Oct 2020 16:13'	System	04 Oct 2020 22:13:15
	System	04 Oct 2020 22:13:15

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	02 Oct 2020 19:57:08
User entered 'Day 4'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	02 Oct 2020 19:57:08
User entered 'Day 5'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	02 Oct 2020 19:57:08
User entered 'Day 6'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	02 Oct 2020 19:57:08
User entered 'Day 7'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-08T21:25:02', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '292ad2d9-7d8b-4a04-bc32-1b3d351241e6'	System	09 Oct 2020 03:25:32
User entered 'None (0)'	System	09 Oct 2020 03:25:32

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-08T21:25:04', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '292ad2d9-7d8b-4a04-bc32-1b3d351241e6' User entered 'None (0)'	System	09 Oct 2020 03:25:32
	System	09 Oct 2020 03:25:32

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-08T21:25:06', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '292ad2d9-7d8b-4a04-bc32-1b3d351241e6'	System	09 Oct 2020 03:25:32
User entered 'None (0)'	System	09 Oct 2020 03:25:32

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-08T21:25:08', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '292ad2d9-7d8b-4a04-bc32-1b3d351241e6' User entered 'None (0)'	System	09 Oct 2020 03:25:32
	System	09 Oct 2020 03:25:32

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-08T21:25:10', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '292ad2d9-7d8b-4a04-bc32-1b3d351241e6' User entered 'None (0)'	System	09 Oct 2020 03:25:32
	System	09 Oct 2020 03:25:32

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-08T21:25:11', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '292ad2d9-7d8b-4a04-bc32-1b3d351241e6' User entered 'None (0)'	System	09 Oct 2020 03:25:32
	System	09 Oct 2020 03:25:32

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:48

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 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-08T21:25:25', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '292ad2d9-7d8b-4a04-bc32-1b3d351241e6'	System	09 Oct 2020 03:25:32
User entered 'No (N)'	System	09 Oct 2020 03:25:32

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-10-08T21:25:28', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '292ad2d9-7d8b-4a04-bc32-1b3d351241e6' User entered '08 Oct 2020 21:25'	System	09 Oct 2020 03:25:32
	System	09 Oct 2020 03:25:32

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 19:57:08

US3892054

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 19:57:08

US3892054

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	15 Oct 2020 23:36:02

US3892054

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	15 Oct 2020 23:36:19
User entered '09 Oct 2020' reason for change: Data Entry Error	System	15 Oct 2020 23:36:19
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	Andryelle Toledo (b) (4)	15 Oct 2020 23:36:19
User entered '04 Oct 2020'	(b) (4)	
	System	15 Oct 2020 23:36:02
	Andryelle Toledo (b) (4)	15 Oct 2020 23:36:02
	(b) (4)	

US3892054

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Andryelle Toledo (b) (4)	15 Oct 2020 23:36:02

US3892054

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Made three attempts on the day 09 Oct. 2020, and another on the day 15 Oct. 2020. No Response.'	(b) (4) Andryelle Toledo (b) (4)	15 Oct 2020 23:36:02

US3892054

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	15 Oct 2020 23:36:25

US3892054

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'I'	System	15 Oct 2020 23:36:25

US3892054

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	22 Oct 2020 19:00:29

US3892054

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:21:22
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with ' Several attempts were made to contact the subject since October 16, 2020. On the date informed, the subject returned the call and the visit was performed by the PA.' (Site from System).	Andryelle Toledo (b) (4) (b) (4)	22 Oct 2020 19:02:13
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	22 Oct 2020 19:00:29
User entered '22 Oct 2020'	Andryelle Toledo (b) (4) (b) (4)	22 Oct 2020 19:00:29

US3892054

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Andryelle Toledo (b) (4)	22 Oct 2020 19:00:29

US3892054

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	22 Oct 2020 19:00:29

US3892054

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	22 Oct 2020 19:00:35

US3892054

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'I'	System	22 Oct 2020 19:00:35

US3892054

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 17:25:52

US3892054

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	23 Oct 2020 17:25:57
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	23 Oct 2020 17:25:57
User entered '23 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 17:25:57
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	23 Oct 2020 17:25:52
User entered '23 Sep 2020'	(b) (4), (b) (6)	23 Oct 2020 17:25:52

US3892054

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 17:25:52

US3892054

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 17:25:52

US3892054

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 17:26:02

US3892054

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'I'	System	23 Oct 2020 17:26:02

US3892054

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:23:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	30 Oct 2020 18:15:34

US3892054

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '30 Oct 2020'	(b) (4) Andryelle Toledo (b) (4)	30 Oct 2020 18:15:34

US3892054

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Clinic (Clinic)'	(b) (4) Andryelle Toledo (b) (4)	30 Oct 2020 18:15:34

US3892054

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:23:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'VISIT3'	System	30 Oct 2020 18:15:34

US3892054

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	30 Oct 2020 19:58:39

US3892054

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '30 Oct 2020'	(b) (4) Andryelle Toledo (b) (4)	30 Oct 2020 19:58:39

US3892054

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '11:14'	(b) (4) Andryelle Toledo (b) (4)	30 Oct 2020 19:58:39

US3892054

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '30 Oct 2020 11:14'	System	30 Oct 2020 19:58:39

US3892054

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '98.6' F	(b) (4) Andryelle Toledo (b) (4)	30 Oct 2020 19:58:39

US3892054

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Oral (Oral)'	(b) (4) Andryelle Toledo (b) (4)	30 Oct 2020 19:58:39

US3892054

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	30 Oct 2020 19:58:39

US3892054

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '84'	Andryelle Toledo (b) (4)	30 Oct 2020 19:58:39

US3892054

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'bpm'	System	30 Oct 2020 19:58:39

US3892054

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '14'	(b) (4) Andryelle Toledo (b) (4)	30 Oct 2020 19:58:39

US3892054

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'breaths/min'	System	30 Oct 2020 19:58:39

US3892054

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	30 Oct 2020 19:58:39

US3892054

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'mmHg'	System	30 Oct 2020 19:58:39

US3892054

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	30 Oct 2020 19:58:39

US3892054

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'mmHg'	System	30 Oct 2020 19:58:39

US3892054

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35

US3892054

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35

US3892054

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:23:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	30 Oct 2020 19:58:55

US3892054

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:23:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '30 Oct 2020'	(b) (4) Andryelle Toledo (b) (4)	30 Oct 2020 19:58:55

US3892054

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:48

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User closed query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 30OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 12:22:36
Query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 30OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' answered with 'Visit 3 was performed, and confirmation of the lab is attached to the chart.' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	04 Dec 2020 01:39:12
User opened query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 30OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 19:07:51
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	30 Oct 2020 19:59:12

US3892054

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '30 Oct 2020'	(b) (4) Andryelle Toledo (b) (4)	30 Oct 2020 19:59:12

US3892054

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:48

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered '11:36'	(b) (4) Andryelle Toledo (b) (4)	30 Oct 2020 19:59:12

US3892054

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '30 Oct 2020 11:36'	System	30 Oct 2020 19:59:12

US3892054

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	30 Oct 2020 19:59:17

US3892054

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'I'	System	30 Oct 2020 19:59:17

US3892054

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered 'Day 64'	System	04 Sep 2020 20:29:05

US3892054

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[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)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-11-04T11:30:47', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '9a8cb318-acbe-4a59-8036-e1d7449145bc' User entered 'No (N)'	System	04 Nov 2020 18:31:04
	System	04 Nov 2020 18:31:04

US3892054

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

Have you been exposed to someone with 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)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-11-04T11:30:54', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '9a8cb318-acbe-4a59-8036-e1d7449145bc'	System	04 Nov 2020 18:31:04
User entered 'No (N)'	System	04 Nov 2020 18:31:04

US3892054

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-11-04T11:30:59', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '9a8cb318-acbe-4a59-8036-e1d7449145bc' User entered '04 Nov 2020 11:30:59'	System	04 Nov 2020 18:31:04
	System	04 Nov 2020 18:31:04

US3892054

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered '04 Nov 2020 00:01'	System	04 Sep 2020 20:29:05

US3892054

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered '08 Nov 2020 23:59'	System	04 Sep 2020 20:29:05

US3892054

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered 'Day 71'	System	04 Sep 2020 20:29:05

US3892054

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[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)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-11-11T07:52:22', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '5167f2d7-4db2-4c44-82f7-48535241e683' User entered 'No (N)'	System	11 Nov 2020 14:52:37
	System	11 Nov 2020 14:52:37

US3892054

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

Have you been exposed to someone with 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)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-11-11T07:52:30', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '5167f2d7-4db2-4c44-82f7-48535241e683'	System	11 Nov 2020 14:52:37
User entered 'No (N)'	System	11 Nov 2020 14:52:37

US3892054

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-11-11T07:52:34', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '5167f2d7-4db2-4c44-82f7-48535241e683' User entered '11 Nov 2020 07:52:34'	System	11 Nov 2020 14:52:37
	System	11 Nov 2020 14:52:37

US3892054

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered '11 Nov 2020 00:01'	System	04 Sep 2020 20:29:05

US3892054

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered '15 Nov 2020 23:59'	System	04 Sep 2020 20:29:05

US3892054

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered 'Day 78'	System	04 Sep 2020 20:29:05

US3892054

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[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)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-11-18T00:01:58', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'a445acb4-cb6f-4368-9b61-16373fddde55'	System	18 Nov 2020 07:02:13
User entered 'No (N)'	System	18 Nov 2020 07:02:13

US3892054

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

Have you been exposed to someone with 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)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-11-18T00:02:05', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'a445acb4-cb6f-4368-9b61-16373fddde55'	System	18 Nov 2020 07:02:13
User entered 'No (N)'	System	18 Nov 2020 07:02:13

US3892054

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-11-18T00:02:08', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'a445acb4-cb6f-4368-9b61-16373fddde55' User entered '18 Nov 2020 00:02:08'	System	18 Nov 2020 07:02:13
	System	18 Nov 2020 07:02:13

US3892054

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered '18 Nov 2020 00:01'	System	04 Sep 2020 20:29:05

US3892054

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:23:02
Data entry locked.	System	04 Sep 2020 20:29:05
User entered '22 Nov 2020 23:59'	System	04 Sep 2020 20:29:05

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-11-25T11:41:08', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'c626493b-8dc1-4b48-ac27-3c8d036d57db' User entered 'No (N)'	System	25 Nov 2020 18:49:34

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Have you been exposed to someone with 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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-11-25T11:49:15', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'c626493b-8dc1-4b48-ac27-3c8d036d57db'	System	25 Nov 2020 18:49:34
User entered 'Yes (Y)'	System	25 Nov 2020 18:49:34

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Please 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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-11-25T11:49:22', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'c626493b-8dc1-4b48-ac27-3c8d036d57db'	System	25 Nov 2020 18:49:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Nov 2020 18:49:34

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-11-25T11:49:25', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'c626493b-8dc1-4b48-ac27-3c8d036d57db' User entered '25 Nov 2020 11:49:25'	System	25 Nov 2020 18:49:34

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-11-29T19:38:48', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '91d5cfd5-0684-475c-a844-964adb9ef42d' User entered 'No (N)'	System	30 Nov 2020 02:39:05

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

Have you been exposed to someone with 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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-11-29T19:38:58', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '91d5cfd5-0684-475c-a844-964adb9ef42d' User entered 'No (N)'	System	30 Nov 2020 02:39:05

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-11-29T19:39:01', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '91d5cfd5-0684-475c-a844-964adb9ef42d' User entered '29 Nov 2020 19:39:01'	System	30 Nov 2020 02:39:05
	System	30 Nov 2020 02:39:05

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-12-06T13:23:12', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '8746b1d7-2a5e-4834-9981-1171e19ef2cf' User entered 'No (N)'	System	06 Dec 2020 20:23:27
	System	06 Dec 2020 20:23:27

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

Have you been exposed to someone with 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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-12-06T13:23:18', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '8746b1d7-2a5e-4834-9981-1171e19ef2cf' User entered 'No (N)'	System	06 Dec 2020 20:23:27
	System	06 Dec 2020 20:23:27

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-12-06T13:23:24', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '8746b1d7-2a5e-4834-9981-1171e19ef2cf' User entered '06 Dec 2020 13:23:24'	System	06 Dec 2020 20:23:27
	System	06 Dec 2020 20:23:27

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-12-14T16:11:01', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'f7556401-4225-4e30-9b7f-81d30a87d3cc'	System	14 Dec 2020 23:11:08
User entered 'No (N)'	System	14 Dec 2020 23:11:08

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

Have you been exposed to someone with 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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-12-14T16:11:04', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'f7556401-4225-4e30-9b7f-81d30a87d3cc'	System	14 Dec 2020 23:11:08
User entered 'No (N)'	System	14 Dec 2020 23:11:08

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-12-14T16:11:07', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'f7556401-4225-4e30-9b7f-81d30a87d3cc' User entered '14 Dec 2020 16:11:07'	System	14 Dec 2020 23:11:08
	System	14 Dec 2020 23:11:08

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-12-21T09:30:47', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '40bda04a-40e3-4db8-a83a-2b89c63232aa' User entered 'No (N)'	System	21 Dec 2020 16:31:00
	System	21 Dec 2020 16:31:00

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

Have you been exposed to someone with 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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-12-21T09:30:54', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '40bda04a-40e3-4db8-a83a-2b89c63232aa' User entered 'No (N)'	System	21 Dec 2020 16:31:00
	System	21 Dec 2020 16:31:00

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-12-21T09:30:57', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '40bda04a-40e3-4db8-a83a-2b89c63232aa' User entered '21 Dec 2020 09:30:57'	System	21 Dec 2020 16:31:00
	System	21 Dec 2020 16:31:00

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-12-27T18:26:40', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '27e8a6d1-e89e-47a9-b0c4-1feeec1c2127' User entered 'No (N)'	System	28 Dec 2020 01:26:47
	System	28 Dec 2020 01:26:47

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

Have you been exposed to someone with 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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-12-27T18:26:42', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '27e8a6d1-e89e-47a9-b0c4-1feec1c2127'	System	28 Dec 2020 01:26:47
User entered 'No (N)'	System	28 Dec 2020 01:26:47

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2020-12-27T18:26:45', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '27e8a6d1-e89e-47a9-b0c4-1feec1c2127' User entered '27 Dec 2020 18:26:45'	System	28 Dec 2020 01:26:47
	System	28 Dec 2020 01:26:47

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-01-04T11:17:25', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'fe8157ed-a7c8-4bdb-b1dd-81645b072d4c' User entered 'No (N)'	System	04 Jan 2021 18:17:37
	System	04 Jan 2021 18:17:37

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

Have you been exposed to someone with 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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-01-04T11:17:29', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'fe8157ed-a7c8-4bdb-b1dd-81645b072d4c'	System	04 Jan 2021 18:17:37
User entered 'No (N)'	System	04 Jan 2021 18:17:37

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-01-04T11:17:32', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'fe8157ed-a7c8-4bdb-b1dd-81645b072d4c' User entered '04 Jan 2021 11:17:32'	System	04 Jan 2021 18:17:37
	System	04 Jan 2021 18:17:37

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-01-14T15:28:04', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'c2b01c7d-b6f4-4dd7-a083-d912c69037a4' User entered 'No (N)'	System	14 Jan 2021 22:28:16
	System	14 Jan 2021 22:28:16

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Have you been exposed to someone with 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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-01-14T15:28:07', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'c2b01c7d-b6f4-4dd7-a083-d912c69037a4' User entered 'No (N)'	System	14 Jan 2021 22:28:16
	System	14 Jan 2021 22:28:16

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-01-14T15:28:11', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'c2b01c7d-b6f4-4dd7-a083-d912c69037a4' User entered '14 Jan 2021 15:28:11'	System	14 Jan 2021 22:28:16
	System	14 Jan 2021 22:28:16

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-01-18T07:41:17', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'f3510ab8-871a-4922-82bc-ad103e20f81f' User entered 'No (N)'	System	18 Jan 2021 14:41:26
	System	18 Jan 2021 14:41:26

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

Have you been exposed to someone with 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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-01-18T07:41:21', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'f3510ab8-871a-4922-82bc-ad103e20f81f'	System	18 Jan 2021 14:41:26
User entered 'No (N)'	System	18 Jan 2021 14:41:26

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-01-18T07:41:24', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'f3510ab8-871a-4922-82bc-ad103e20f81f' User entered '18 Jan 2021 07:41:24'	System	18 Jan 2021 14:41:26
	System	18 Jan 2021 14:41:26

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-01-24T16:41:48', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '8c8f09e7-871e-4720-9cf6-12575b3c3a15'	System	24 Jan 2021 23:41:58
User entered 'No (N)'	System	24 Jan 2021 23:41:58

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

Have you been exposed to someone with 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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-01-24T16:41:52', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '8c8f09e7-871e-4720-9cf6-12575b3c3a15'	System	24 Jan 2021 23:41:58
User entered 'No (N)'	System	24 Jan 2021 23:41:58

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-01-24T16:41:55', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '8c8f09e7-871e-4720-9cf6-12575b3c3a15'	System	24 Jan 2021 23:41:58
User entered '24 Jan 2021 16:41:55'	System	24 Jan 2021 23:41:58

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-01-31T09:28:50', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'd8a7e3e7-87bd-4ca6-8880-1b6499e31dd9' User entered 'No (N)'	System	31 Jan 2021 16:29:10
	System	31 Jan 2021 16:29:10

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

Have you been exposed to someone with 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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-01-31T09:29:02', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'd8a7e3e7-87bd-4ca6-8880-1b6499e31dd9'	System	31 Jan 2021 16:29:10
User entered 'No (N)'	System	31 Jan 2021 16:29:10

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-01-31T09:29:05', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'd8a7e3e7-87bd-4ca6-8880-1b6499e31dd9' User entered '31 Jan 2021 09:29:05'	System	31 Jan 2021 16:29:10
	System	31 Jan 2021 16:29:10

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-02-09T09:49:58', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '3b18ad8c-39ae-4c1d-b945-0c5ed7ccc0b3' User entered 'No (N)'	System	09 Feb 2021 16:50:07
	System	09 Feb 2021 16:50:07

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

Have you been exposed to someone with 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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-02-09T09:50:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '3b18ad8c-39ae-4c1d-b945-0c5ed7ccc0b3' User entered 'No (N)'	System	09 Feb 2021 16:50:07

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-02-09T09:50:03', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '3b18ad8c-39ae-4c1d-b945-0c5ed7ccc0b3' User entered '09 Feb 2021 09:50:03'	System	09 Feb 2021 16:50:07
	System	09 Feb 2021 16:50:07

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-02-14T19:39:51', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '24f2ee3b-6828-4aa0-98d3-7a78f1d871f9'	System	15 Feb 2021 02:39:58
User entered 'No (N)'	System	15 Feb 2021 02:39:58

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

Have you been exposed to someone with 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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-02-14T19:39:53', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '24f2ee3b-6828-4aa0-98d3-7a78f1d871f9'	System	15 Feb 2021 02:39:58
User entered 'No (N)'	System	15 Feb 2021 02:39:58

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-02-14T19:39:55', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '24f2ee3b-6828-4aa0-98d3-7a78f1d871f9' User entered '14 Feb 2021 19:39:55'	System	15 Feb 2021 02:39:58
	System	15 Feb 2021 02:39:58

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-02-25T17:08:50-07:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '67317f6f-4d17-4bcc-bc3c-b4281c95e493'	System	26 Feb 2021 00:14:54
User entered 'No (N)'	System	26 Feb 2021 00:14:54

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Have you been exposed to someone with 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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-02-25T17:08:56-07:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '67317f6f-4d17-4bcc-bc3c-b4281c95e493'	System	26 Feb 2021 00:14:54
User entered 'No (N)'	System	26 Feb 2021 00:14:54

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-02-25T17:08:58-07:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '67317f6f-4d17-4bcc-bc3c-b4281c95e493'	System	26 Feb 2021 00:14:54
User entered '26 Feb 2021 00:08:58'	System	26 Feb 2021 00:14:54

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-03-01T00:55:32-07:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '39f43770-bb95-4a0a-aa70-1a0e91afc751'	System	01 Mar 2021 07:55:41
User entered 'No (N)'	System	01 Mar 2021 07:55:41

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Have you been exposed to someone with 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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-03-01T00:55:34-07:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '39f43770-bb95-4a0a-aa70-1a0e91afc751'	System	01 Mar 2021 07:55:41
User entered 'No (N)'	System	01 Mar 2021 07:55:41

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-03-01T00:55:37-07:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '39f43770-bb95-4a0a-aa70-1a0e91afc751' User entered '01 Mar 2021 00:55:37'	System	01 Mar 2021 07:55:41
	System	01 Mar 2021 07:55:41

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-03-08T08:46:49-07:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '70f28d7e-dafc-46bf-a466-9eefc7d40f75'	System	08 Mar 2021 15:48:10
User entered 'Yes (Y)'	System	08 Mar 2021 15:48:10

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

Have you been exposed to someone with 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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-03-08T08:46:57-07:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '70f28d7e-dafc-46bf-a466-9eefc7d40f75'	System	08 Mar 2021 15:48:10
User entered 'No (N)'	System	08 Mar 2021 15:48:10

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-03-08T08:47:47-07:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '70f28d7e-dafc-46bf-a466-9eefc7d40f75'	System	08 Mar 2021 15:48:10
User entered 'No (N)'	System	08 Mar 2021 15:48:10

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-03-08T08:47:59-07:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '70f28d7e-dafc-46bf-a466-9eefc7d40f75'	System	08 Mar 2021 15:48:10
User entered 'No (N)'	System	08 Mar 2021 15:48:10

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-03-08T08:48:04-07:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '70f28d7e-dafc-46bf-a466-9eefc7d40f75'	System	08 Mar 2021 15:48:10
User entered '08 Mar 2021 08:48:04'	System	08 Mar 2021 15:48:10

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-04-01T09:38:33-06:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'ffc1d51f-e954-4dd4-83ae-06faa8e9ff03'	System	01 Apr 2021 15:38:46
User entered 'No (N)'	System	01 Apr 2021 15:38:46

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

Have you been exposed to someone with 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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-04-01T09:37:57-06:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'ffc1d51f-e954-4dd4-83ae-06faa8e9ff03'	System	01 Apr 2021 15:38:46
User entered 'No (N)'	System	01 Apr 2021 15:38:46

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-04-01T09:38:41-06:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'ffc1d51f-e954-4dd4-83ae-06faa8e9ff03'	System	01 Apr 2021 15:38:46
User entered '01 Apr 2021 09:38:41'	System	01 Apr 2021 15:38:46

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-04-06T13:10:12-06:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '3fde12a1-9518-4eca-acb2-d61ed05b7dcd' User entered 'No (N)'	System	06 Apr 2021 19:10:22
	System	06 Apr 2021 19:10:22

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

Have you been exposed to someone with 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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-04-06T13:10:15-06:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '3fde12a1-9518-4eca-acb2-d61ed05b7dcd' User entered 'No (N)'	System	06 Apr 2021 19:10:22
	System	06 Apr 2021 19:10:22

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-04-06T13:10:18-06:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '3fde12a1-9518-4eca-acb2-d61ed05b7dcd' User entered '06 Apr 2021 13:10:18'	System	06 Apr 2021 19:10:22
	System	06 Apr 2021 19:10:22

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-04-11T19:12:43-06:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '8737ec23-09c0-4ccc-b65f-06212f783af6'	System	12 Apr 2021 01:17:03
User entered 'No (N)'	System	12 Apr 2021 01:17:03

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Have you been exposed to someone with 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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-04-11T19:12:48-06:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '8737ec23-09c0-4ccc-b65f-06212f783af6'	System	12 Apr 2021 01:17:03
User entered 'No (N)'	System	12 Apr 2021 01:17:03

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-04-11T19:12:51-06:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '8737ec23-09c0-4ccc-b65f-06212f783af6'	System	12 Apr 2021 01:17:03
User entered '11 Apr 2021 19:12:51'	System	12 Apr 2021 01:17:03

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-04-20T11:10:02-06:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '3c991bc7-1477-4a5b-94cf-322f0a0cf87f' User entered 'No (N)'	System	20 Apr 2021 17:10:27
	System	20 Apr 2021 17:10:27

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

Have you been exposed to someone with 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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-04-20T11:10:11-06:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '3c991bc7-1477-4a5b-94cf-322f0a0cf87f' User entered 'No (N)'	System	20 Apr 2021 17:10:27

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-04-20T11:10:20-06:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '3c991bc7-1477-4a5b-94cf-322f0a0cf87f' User entered '20 Apr 2021 11:10:20'	System	20 Apr 2021 17:10:27
	System	20 Apr 2021 17:10:27

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-04-26T23:06:42-06:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '01ad337d-41fd-4706-91b1-526a44b14d70'	System	27 Apr 2021 05:08:09
User entered 'No (N)'	System	27 Apr 2021 05:08:09

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

Have you been exposed to someone with 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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-04-26T23:07:21-06:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '01ad337d-41fd-4706-91b1-526a44b14d70'	System	27 Apr 2021 05:08:09
User entered 'No (N)'	System	27 Apr 2021 05:08:09

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-04-26T23:08:06-06:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: '01ad337d-41fd-4706-91b1-526a44b14d70'	System	27 Apr 2021 05:08:09
User entered '26 Apr 2021 23:08:06'	System	27 Apr 2021 05:08:09

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-05-02T05:25:45-06:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'e08983f3-66f5-4ee8-a1d5-a625504be787'	System	02 May 2021 11:25:56
User entered 'No (N)'	System	02 May 2021 11:25:56

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

Have you been exposed to someone with 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 (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-05-02T05:25:50-06:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'e08983f3-66f5-4ee8-a1d5-a625504be787'	System	02 May 2021 11:25:56
User entered 'No (N)'	System	02 May 2021 11:25:56

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-05-02T05:25:53-06:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'e08983f3-66f5-4ee8-a1d5-a625504be787'	System	02 May 2021 11:25:56
User entered '02 May 2021 05:25:53'	System	02 May 2021 11:25:56

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 04:08:25

US3892054

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:08:25
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 04:08:25

US3892054

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:23:48

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)	25 Apr 2021 21:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-03-01T00:55:44-07:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'd2803d59-c1a4-4745-8f25-5a8f0e6b5664'	System	01 Mar 2021 07:55:51
User entered 'No (N)'	System	01 Mar 2021 07:55:51

US3892054

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:23:48

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE29A09B-5EEF-4583-B868-BA82B867DA5F)', Time: '2021-03-01T00:55:48-07:00', User OID: 'PatientReportedOutcome (US3892054)', ODM File OID: 'd2803d59-c1a4-4745-8f25-5a8f0e6b5664' User entered '01 Mar 2021 00:55:48'	System	01 Mar 2021 07:55:51
	System	01 Mar 2021 07:55:51

US3892054

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	04 Dec 2020 14:50:19

US3892054

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered '25 Nov 2020'	(b) (4) Andryelle Toledo (b) (4)	04 Dec 2020 14:50:19

US3892054

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Andryelle Toledo (b) (4)	04 Dec 2020 14:50:19

US3892054

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	04 Dec 2020 14:50:19

US3892054

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	04 Dec 2020 14:50:23

US3892054

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'I'	System	04 Dec 2020 14:50:23

US3892054

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:37:06
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 23:16:23
User entered 'Yes (Y)'	Courtney Jensen (b) (4) (b) (4)	30 Dec 2020 21:32:39

US3892054

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:37:06
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 23:16:23
User entered '29 Dec 2020'	Courtney Jensen (b) (4) (b) (4)	30 Dec 2020 21:32:39

US3892054

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:37:06
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 23:16:23
User entered 'Contact Made (CONTACT MADE)'	Courtney Jensen (b) (4) (b) (4)	30 Dec 2020 21:32:39

US3892054

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:37:06
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 23:16:23
User entered empty.	Courtney Jensen (b) (4) (b) (4)	30 Dec 2020 21:32:39

US3892054

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:37:06
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 23:16:38
User entered 'Yes (Y)'	Courtney Jensen (b) (4) (b) (4)	30 Dec 2020 21:33:06

US3892054

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:37:06
User entered 'I'	System	30 Dec 2020 21:33:06

US3892054

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:37:06
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	27 Jan 2021 16:09:04

US3892054

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:37:06
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered '27 Jan 2021'	(b) (4) Andryelle Toledo (b) (4)	27 Jan 2021 16:09:04

US3892054

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:37:06
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Andryelle Toledo (b) (4)	27 Jan 2021 16:09:04

US3892054

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:37:06
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered empty.	Andryelle Toledo (b) (4)	27 Jan 2021 16:09:04

US3892054

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:37:06
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	27 Jan 2021 16:09:08

US3892054

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:37:06
User entered 'I'	System	27 Jan 2021 16:09:08

US3892054

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:50:54
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:31:14
	(b) (4)	

US3892054

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:50:54
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered '02 Mar 2021'	Andryelle Toledo (b) (4)	02 Mar 2021 22:31:14
	(b) (4)	

US3892054

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	30 Apr 2021 18:50:54
User signature succeeded.	Michael Adams (b) (4) (b) (4)	12 Apr 2021 16:27:14
User entered 'Contact Made (CONTACT MADE)'	Andryelle Toledo (b) (4) (b) (4)	02 Mar 2021 22:31:14

US3892054

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:50:54
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:31:14
	(b) (4)	

US3892054

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:50:54
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:31:18
	(b) (4)	

US3892054

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:50:54
User entered 'I'	System	02 Mar 2021 22:31:18

US3892054

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:23:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'Yes (Y)'	Rachel Law (b) (4)	02 Apr 2021 18:40:24
	(b) (4)	

US3892054

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered '2 Apr 2021'	Rachel Law (b) (4)	02 Apr 2021 18:40:24
	(b) (4)	

US3892054

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'Clinic (Clinic)'	Rachel Law (b) (4)	02 Apr 2021 18:40:24
	(b) (4)	

US3892054

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:23:48

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	02 Apr 2021 18:40:24

US3892054

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'No (N)'	Rachel Law (b) (4)	02 Apr 2021 18:40:59
	(b) (4)	

US3892054

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	Rachel Law (b) (4)	02 Apr 2021 18:40:59
	(b) (4)	

US3892054

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	Rachel Law (b) (4)	02 Apr 2021 18:40:59
	(b) (4)	

US3892054

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 18:40:59

US3892054

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	Rachel Law (b) (4)	02 Apr 2021 18:40:59
	(b) (4)	

US3892054

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	Rachel Law (b) (4)	02 Apr 2021 18:40:59
	(b) (4)	

US3892054

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	Rachel Law (b) (4)	02 Apr 2021 18:40:59
	(b) (4)	

US3892054

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	Rachel Law (b) (4)	02 Apr 2021 18:40:59
	(b) (4)	

US3892054

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 18:40:59

US3892054

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	Rachel Law (b) (4)	02 Apr 2021 18:40:59
	(b) (4)	

US3892054

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 18:40:59

US3892054

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	Rachel Law (b) (4)	02 Apr 2021 18:40:59
	(b) (4)	

US3892054

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 18:40:59

US3892054

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	Rachel Law (b) (4)	02 Apr 2021 18:40:59
	(b) (4)	

US3892054

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 18:40:59

US3892054

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:23:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'Yes (Y)'	Rachel Law (b) (4)	02 Apr 2021 18:41:14
	(b) (4)	

US3892054

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:23:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered '2 Apr 2021'	Rachel Law (b) (4)	02 Apr 2021 18:41:14
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'Yes (Y)'	Rachel Law (b) (4)	02 Apr 2021 18:42:41
	(b) (4)	

US3892054

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered '2 Apr 2021'	Rachel Law (b) (4)	02 Apr 2021 18:42:41
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered '11:33'	Rachel Law (b) (4)	02 Apr 2021 18:42:41
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
User entered '2 Apr 2021 11:33'	System	02 Apr 2021 18:42:41

US3892054

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'Yes (Y)'	Rachel Law (b) (4)	02 Apr 2021 18:42:45
	(b) (4)	

US3892054

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 18:42:45

US3892054

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

Form: Visit Date

Generated On: 10 Jun 2021 10:23:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:11
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 00:01:58

US3892054

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

Form: Visit Date

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:11
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 00:01:58

US3892054

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

Form: Visit Date

Generated On: 10 Jun 2021 10:23:48

[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 19:36:11
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 00:01:58

US3892054

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

Form: Visit Date

Generated On: 10 Jun 2021 10:23:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:11
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 00:01:58

US3892054

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

Form: Unblinding

Generated On: 10 Jun 2021 10:23:48

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:11
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 00:03:03

US3892054

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

Form: Unblinding

Generated On: 10 Jun 2021 10:23:48

[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 19:36:11
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	31 Mar 2021 22:27:03
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 18:39:49

US3892054

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

Form: Unblinding

Generated On: 10 Jun 2021 10:23:48

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:11
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 00:03:03

US3892054

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

Form: Unblinding

Generated On: 10 Jun 2021 10:23:48

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:11
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User closed query 'Kindly update EDC. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:55:17
Query 'Kindly update EDC. ' answered with 'Update' (Site from CRA).	Andryelle Toledo (b) (4) (b) (4)	31 Mar 2021 22:27:15
User entered 'Amendment 6 or later (Amendment 6 or later)'	Andryelle Toledo (b) (4) (b) (4)	31 Mar 2021 22:27:03
User opened query 'Kindly update EDC. ' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 16:54:02
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:39:49

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

Form: Unblinding

Generated On: 10 Jun 2021 10:23:48

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:11
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 00:03:03

US3892054

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

Form: Unblinding

Generated On: 10 Jun 2021 10:23:48

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:11
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 00:03:03

US3892054

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

Form: Unblinding

Generated On: 10 Jun 2021 10:23:48

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:11
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 14:10:55
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	15 Jan 2021 00:03:03

US3892054

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

Form: Unblinding

Generated On: 10 Jun 2021 10:23:48

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:11
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 14:10:55
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	15 Jan 2021 00:03:03

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

Form: Unblinding

Generated On: 10 Jun 2021 10:23:48

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:11
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 00:03:03

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

Form: Unblinding

Generated On: 10 Jun 2021 10:23:48

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:11
User entered empty.	System	15 Jan 2021 00:03:03

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

Form: Unblinding

Generated On: 10 Jun 2021 10:23:48

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:11
User entered empty.	System	15 Jan 2021 00:03:03

US3892054

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:11
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 00:04:08

US3892054

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:11
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 00:04:08

US3892054

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:11
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	15 Jan 2021 00:04:25
User entered '15:44' reason for change: Data Entry Error	System	15 Jan 2021 00:04:25
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	15 Jan 2021 00:04:08
User entered '15:' (non-conformant).	System	15 Jan 2021 00:04:08
	(b) (4), (b) (6)	15 Jan 2021 00:04:08

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:11
User entered '14 Jan 2021 15:44'	System	15 Jan 2021 00:04:25
User entered '14 Jan 2021 15:' (non-conformant).	System	15 Jan 2021 00:04:08

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:23:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:11
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 00:04:50

US3892054

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:11
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 00:04:50

US3892054

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:23:48

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:11
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered '15:53'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 00:04:50

US3892054

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:11
User entered '14 Jan 2021 15:53'	System	15 Jan 2021 00:04:50

US3892054

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:23:48

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:02:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:56:00
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
Signature has been broken.	(b) (4)	
	Andryelle Toledo (b) (4)	02 Mar 2021 22:31:39
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	02 Mar 2021 22:31:39
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:56:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:48

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 18:57:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:12:12
User entered	System	05 Apr 2021 15:12:06
'USA-US209-2021-mRNA-1273-P301000004'		
User entered 'New'	(b) (4), (b) (6)	05 Apr 2021 15:12:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:48

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:57:22
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
User coded data point as SOC: Psychiatric disorders, HLT: Depressive disorders, PT: Depression, LLT: Depression worsened - version MedDRA\\23.0.	Coder Import (b) (4)	02 Mar 2021 22:33:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Mar 2021 22:33:47
Data point term sent to Coder	System	02 Mar 2021 22:32:30
User entered 'Worsening of Depression'	Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:57:30
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:57:33
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:57:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:57:39
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
User entered '01 Feb 2021'	Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20

US3892054

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:57:43
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20

US3892054

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 22:32:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
	(b) (4)	
DataPoint Un-verified.	Andryelle Toledo (b) (4)	15 Apr 2021 19:41:03
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	15 Apr 2021 19:41:03
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	15 Apr 2021 19:41:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:57:45
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:55:20
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' answered with 'Update narrative' (Site from Safety).	Andryelle Toledo (b) (4) (b) (4)	15 Apr 2021 19:41:48
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	15 Apr 2021 19:41:19
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	15 Apr 2021 19:41:19
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	15 Apr 2021 19:41:03
DataPoint Un-verified.	Andryelle Toledo (b) (4) (b) (4)	15 Apr 2021 19:41:03
Signature has been broken.	Andryelle Toledo (b) (4) (b) (4)	15 Apr 2021 19:41:03
User entered '25 Mar 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	15 Apr 2021 19:41:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:58:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 11:06:51
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:58:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20

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Folder: Adverse Events

Form: Adverse Events (1)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 22:32:20

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:58:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20

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Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 18:58:29
Signature has been broken.	Rachel Law (b) (4)	02 Apr 2021 18:47:09
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Rachel Law (b) (4)	02 Apr 2021 18:47:09
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20
	(b) (4)	

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Folder: Adverse Events

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:58:32
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20

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Folder: Adverse Events

Form: Adverse Events (1)

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:58:43
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:00:14
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	02 Apr 2021 19:09:10
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	02 Apr 2021 19:09:10
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	02 Apr 2021 18:47:09
Signature has been broken.	Rachel Law (b) (4)	02 Apr 2021 18:47:09
User entered '1' reason for change: Data Entry Error	(b) (4) Rachel Law (b) (4)	02 Apr 2021 18:47:09
User signature succeeded.	(b) (4) Michael Adams (b) (4)	15 Mar 2021 16:22:01
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:00:25
Signature has been broken.	Rachel Law (b) (4)	02 Apr 2021 18:47:09
	(b) (4)	
User entered '20 Mar 2021' reason for change: Data Entry Error	Rachel Law (b) (4)	02 Apr 2021 18:47:09
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:00:27
Signature has been broken.	Rachel Law (b) (4)	02 Apr 2021 18:47:09
	(b) (4)	
User entered '25 Mar 2021' reason for change: Data Entry Error	Rachel Law (b) (4)	02 Apr 2021 18:47:09
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:00:42
Signature has been broken.	Rachel Law (b) (4)	02 Apr 2021 19:09:10
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Rachel Law (b) (4)	02 Apr 2021 19:09:10
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20
	(b) (4)	

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:00:43
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:00:45
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:00:54
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:06
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:00:57
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20

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Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:08
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20

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Folder: Adverse Events

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:16
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20

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Folder: Adverse Events

Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:19
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
User entered 'I'	Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:55:22
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' answered with 'Update narrative' (Site from Safety).	Andryelle Toledo (b) (4) (b) (4)	15 Apr 2021 19:41:59
DataPoint Un-verified.	Andryelle Toledo (b) (4) (b) (4)	15 Apr 2021 19:41:19
Signature has been broken.	Andryelle Toledo (b) (4) (b) (4)	15 Apr 2021 19:41:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Andryelle Toledo (b) (4) (b) (4)	15 Apr 2021 19:41:19
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:26
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 11:07:01
User signature succeeded.	Michael Adams (b) (4) (b) (4)	15 Mar 2021 16:22:01
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Andryelle Toledo (b) (4) (b) (4)	02 Mar 2021 22:32:20

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:29
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
User closed 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) (4), (b) (6)	16 Apr 2021 16:55:26
User closed 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)	16 Apr 2021 16:55:24
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. ' answered with 'I sent medical records via fax today 15 APR 2021. I updated the narrative and the COVID-19 test (Saliva) is Negative.' (Site from Safety).	Andryelle Toledo (b) (4) (b) (4)	15 Apr 2021 20:25:12
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. ' answered with 'I faxed the medical records today 15 APR 2021' (Site from Safety).	Andryelle Toledo (b) (4) (b) (4)	15 Apr 2021 20:24:27
DataPoint Un-verified.	Andryelle Toledo (b) (4) (b) (4)	15 Apr 2021 19:41:03

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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT REPORTS SIGNIFICANT STRESS INCLUDING FINANCIAL, LEGAL AND RELATIONSHIP, EMOTIONAL ISSUES. THIS LED HER TO FEEL THAT SHE NEEDED "A BREAK FROM LIFE." SHE HAD SUICIDAL IDEATIONS AND WAS ADMITTED TO A MENTAL HEALTH INPATIENT HOSPITAL FROM 20MAR2021 TO 25MAR2021. DURING THIS ADMISSION, CELEXA WAS STOPPED AND PAROXETINE WAS STARTED. BUSPIRONE WAS INCREASED FROM 20 MG BID TO 30 MG BID. SHE CURRENTLY HAS NO SUICIDAL IDEATIONS. SHE REPORTS SOME DEPRESSION, INSOMNIA, FATIGUE, POOR CONCENTRATION, AND FEELING OVERWHELMED BUT THESE SYMPTOMS ARE MUCH IMPROVED FROM 2 WEEKS AGO. 15 APR 21: Per medical records symptoms returned to baseline upon discharge. 21 Mar 2021: Specimen Collected - Saliva. 22 Mar 2021 - COVID19 PCR Not Detected' reason for change: Data Entry Error DataPoint Verified.	Andryelle Toledo (b) (4) (b) (4)	15 Apr 2021 19:41:03
	(b) (4), (b) (6)	12 Apr 2021 19:01:31
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)	12 Apr 2021 11:07:18
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)	12 Apr 2021 11:07:09
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	02 Apr 2021 19:07:28

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[Narrative](#)

Audit	User	Time (GMT)
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	02 Apr 2021 19:07:28
Signature has been broken.	Rachel Law (b) (4)	02 Apr 2021 19:07:28
User entered 'Subject reports significant stress including financial, legal and relationship, emotional issues. This led her to feel that she needed "a break from life." She had suicidal ideations and was admitted to a mental health inpatient hospital from 20Mar2021 to 25Mar2021. During this admission, Celexa was stopped and paroxetine was started. Buspirone was increased from 20 mg BID to 30 mg BID. She currently has no suicidal ideations. She reports some depression, insomnia, fatigue, poor concentration, and feeling overwhelmed but these symptoms are much improved from 2 weeks ago.' reason for change: Data Entry Error	Rachel Law (b) (4)	02 Apr 2021 19:07:28
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	02 Apr 2021 18:47:09
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:32:20

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Folder: Adverse Events

Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 18:47:09
User entered '0'	System	02 Mar 2021 22:32:20

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Mar 2021 22:32:20

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Apr 2021 19:09:10

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	02 Mar 2021 22:34:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Mar 2021 22:34:52
Data point term sent to Coder	System	02 Mar 2021 22:33:31
User entered 'Worsening of Anxiety'	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	02 Mar 2021 22:33:15
User entered '17 Sep 2020' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:15
	(b) (4)	
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	02 Mar 2021 22:33:02
User entered '17 Sep 2021'	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02
	(b) (4)	

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Form: Adverse Events (2)

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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02
	(b) (4)	

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 22:33:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02
	(b) (4)	

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02
	(b) (4)	

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 22:33:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:48

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02

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Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4) (b) (4)	15 Mar 2021 16:22:01
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	02 Mar 2021 22:33:02

US3892054

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:48

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4) (b) (4)	15 Mar 2021 16:22:01
User entered '1'	Andryelle Toledo (b) (4) (b) (4)	02 Mar 2021 22:33:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:48

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:48

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:48

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:22:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:33:02
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Mar 2021 22:33:02

US3892054

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Mar 2021 22:33:02

US3892054

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 19:47:02
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 19:47:02
	(b) (4)	
Data point term sent to Coder	System	15 Apr 2021 19:45:21
User entered 'Urinary Tract Infection'	Andryelle Toledo (b) (4)	15 Apr 2021 19:44:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	15 Apr 2021 19:44:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	15 Apr 2021 19:44:35
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	15 Apr 2021 19:44:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
	(b) (4)	
User entered '24 Mar 2021'	Andryelle Toledo (b) (4)	15 Apr 2021 19:44:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	15 Apr 2021 19:44:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:44:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	15 Apr 2021 19:44:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	15 Apr 2021 19:44:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	15 Apr 2021 19:44:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:44:35

US3892054

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Andryelle Toledo (b) (4)	15 Apr 2021 19:44:35
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	15 Apr 2021 19:44:35
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	15 Apr 2021 19:44:35
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	15 Apr 2021 19:44:35
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	15 Apr 2021 19:44:35
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4) (b) (4)	19 Apr 2021 16:03:28
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	15 Apr 2021 19:44:35

US3892054

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4) (b) (4)	19 Apr 2021 16:03:28
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	15 Apr 2021 19:44:35

US3892054

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4) (b) (4)	19 Apr 2021 16:03:28
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	15 Apr 2021 19:44:35

US3892054

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	15 Apr 2021 19:44:35
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	15 Apr 2021 19:44:35
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	15 Apr 2021 19:44:35
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4) (b) (4)	19 Apr 2021 16:03:28
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	15 Apr 2021 19:44:35

US3892054

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4)	15 Apr 2021 19:44:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4)	15 Apr 2021 19:44:35
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Andryelle Toledo (b) (4)	15 Apr 2021 19:44:35
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	15 Apr 2021 19:44:35
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4) (b) (4)	19 Apr 2021 16:03:28
User entered '1'	Andryelle Toledo (b) (4) (b) (4)	15 Apr 2021 19:44:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4) (b) (4)	19 Apr 2021 16:03:28
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	15 Apr 2021 19:44:35

US3892054

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Andryelle Toledo (b) (4)	15 Apr 2021 19:44:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	15 Apr 2021 19:44:35
	(b) (4)	

US3892054

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4) (b) (4)	19 Apr 2021 16:03:28
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	15 Apr 2021 19:44:35

US3892054

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Apr 2021 19:44:35

US3892054

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:23:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 19:44:35

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:23:48

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:02:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:50:51

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: ARIPIPRAZOLE, PRODUCTSYNONYM: ABILIFY - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Oct 2020 21:53:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 21:53:51
Data point term sent to Coder	System	02 Oct 2020 21:52:46
User entered 'Abilify'	Andryelle Toledo (b) (4) (b) (4)	02 Oct 2020 21:51:53

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:51:53
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'depression'	Andryelle Toledo (b) (4)	02 Oct 2020 21:51:53
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	15 Apr 2021 19:47:39
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered '10'	Andryelle Toledo (b) (4)	02 Oct 2020 21:51:53
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'mg (mg)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:51:53
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Oct 2020 21:51:53
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'once daily (QD)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:51:53
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Oct 2020 21:51:53
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'Oral (ORAL)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:51:53
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Oct 2020 21:51:53
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'un Jun 2020'	Andryelle Toledo (b) (4)	02 Oct 2020 21:51:53
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	02 Oct 2020 21:51:53
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:51:53
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Oct 2020 21:51:53
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:51:53
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 21:51:53

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 21:51:53

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 21:51:53

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:49
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM HYDROBROMIDE, PRODUCTSYNONYM: CELEXA [CITALOPRAM HYDROBROMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 21:54:51
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	02 Oct 2020 21:54:51
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	02 Oct 2020 21:53:47
User entered 'celexa'	Andryelle Toledo (b) (4)	02 Oct 2020 21:53:27
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:49
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:53:27
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:49
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'depression'	Andryelle Toledo (b) (4)	02 Oct 2020 21:53:27
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:49
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered '20' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	02 Mar 2021 22:34:15
	(b) (4)	
User entered '40'	Andryelle Toledo (b) (4)	02 Oct 2020 21:53:27
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:49
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'mg (mg)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:53:27
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:49
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Oct 2020 21:53:27
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:49
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'once daily (QD)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:53:27
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:49
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Oct 2020 21:53:27
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:49
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'Oral (ORAL)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:53:27
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:49
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Oct 2020 21:53:27
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:48

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:49
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'un Jun 2020'	Andryelle Toledo (b) (4)	02 Oct 2020 21:53:27
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:49
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	02 Oct 2020 21:53:27
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:49
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	02 Mar 2021 22:35:14
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:53:27
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:49
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered '10 Feb 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	02 Mar 2021 22:35:14
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Oct 2020 21:53:27
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:49
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:53:27
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:49
User entered '1'	System	02 Oct 2020 21:53:27

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:49
User entered '1'	System	02 Oct 2020 21:53:27

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:49
User entered '804 (804)'	System	02 Oct 2020 21:53:27

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: DIPHENYLMETHANE DERIVATIVES, PRODUCT: HYDROXYZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 21:55:52
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 21:55:52
	(b) (4)	
Data point term sent to Coder	System	02 Oct 2020 21:54:48
User entered 'Vistaril'	Andryelle Toledo (b) (4)	02 Oct 2020 21:54:42
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:54:42
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'Anxiety'	Andryelle Toledo (b) (4)	02 Oct 2020 21:54:42
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered '50'	Andryelle Toledo (b) (4)	02 Oct 2020 21:54:42
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'mg (mg)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:54:42
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Oct 2020 21:54:42
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'once daily (QD)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:54:42
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Oct 2020 21:54:42
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'Oral (ORAL)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:54:42
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Oct 2020 21:54:42
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'un Jun 2020'	Andryelle Toledo (b) (4)	02 Oct 2020 21:54:42
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	02 Oct 2020 21:54:42
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 00:18:37
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:54:42
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered '15 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 00:18:37
User entered empty.	Andryelle Toledo (b) (4)	02 Oct 2020 21:54:42
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:54:42
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:53
User entered '1'	System	02 Oct 2020 21:54:42

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:53
User entered '1'	System	02 Oct 2020 21:54:42

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:53
User entered '804 (804)'	System	02 Oct 2020 21:54:42

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: NORETHISTERONE, PRODUCTSYNONYM: NORETHINDRONE [NORETHISTERONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 22:18:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 22:18:59
Data point term sent to Coder	System	15 Jan 2021 22:17:52
User closed query 'For coding purposes, add medication ingredients, or if ingredients are unknown please add (INGREDIENTS UNKNOWN) after the reported medication to enable coding' (Site from System).	System	15 Jan 2021 22:17:12
Query 'For coding purposes, add medication ingredients, or if ingredients are unknown please add (INGREDIENTS UNKNOWN) after the reported medication to enable coding' answered with 'updated ingredients' (Site from System).	Leslie Iverson (b) (4)	15 Jan 2021 22:17:12
User entered 'Norethindrone' reason for change: Data Entry Error	Leslie Iverson (b) (4)	15 Jan 2021 22:16:57
User opened query 'For coding purposes, add medication ingredients, or if ingredients are unknown please add (INGREDIENTS UNKNOWN) after the reported medication to enable coding' (Site from System).	Coder Import (b) (4)	31 Dec 2020 00:01:24
Data point term sent to Coder	System	04 Dec 2020 01:38:42
User closed query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	System	04 Dec 2020 01:38:25

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:48

[Name of Medication](#)

Audit	User	Time (GMT)
Query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' answered with 'The medication name is correct' (Site from System).	Andryelle Toledo (b) (4)	04 Dec 2020 01:38:25
User opened query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	23 Nov 2020 12:42:50
Data point term sent to Coder	System	02 Oct 2020 21:56:51
User entered 'Pandia Health'	Andryelle Toledo (b) (4)	02 Oct 2020 21:56:03

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User closed query 'Per DM CLR:Indication is birth control however Prophylaxis=NO. Please review entry on "Prophylaxis" accordingly or provide clarification ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 06:29:28
Query 'Per DM CLR:Indication is birth control however Prophylaxis=NO. Please review entry on "Prophylaxis" accordingly or provide clarification ' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	04 Dec 2020 01:37:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	04 Dec 2020 01:37:48
User opened query 'Per DM CLR:Indication is birth control however Prophylaxis=NO. Please review entry on "Prophylaxis" accordingly or provide clarification ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 05:47:51
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	02 Oct 2020 21:56:03

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'Birth control'	Andryelle Toledo (b) (4)	02 Oct 2020 21:56:03
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered '0.35' reason for change: New Information	Leslie Iverson (b) (4)	15 Jan 2021 22:16:57
	(b) (4)	
User entered '1'	Andryelle Toledo (b) (4)	02 Oct 2020 21:56:03
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'mg (mg)' reason for change: New Information	Leslie Iverson (b) (4)	15 Jan 2021 22:16:57
	(b) (4)	
User entered 'tablet (TABLET)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:56:03
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Oct 2020 21:56:03
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'once daily (QD)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:56:03
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Oct 2020 21:56:03
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'Oral (ORAL)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:56:03
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Oct 2020 21:56:03
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'un Jun 2020'	Andryelle Toledo (b) (4)	02 Oct 2020 21:56:03
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	02 Oct 2020 21:56:03
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:56:03
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Oct 2020 21:56:03
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:56:03
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 21:56:03

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 21:56:03

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 21:56:03

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:58
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 22:37:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 22:37:48
	(b) (4)	
Data point term sent to Coder	System	02 Mar 2021 22:36:33
Coding entries removed.	Andryelle Toledo (b) (4)	02 Mar 2021 22:35:33
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 00:15:59
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 00:15:59
	(b) (4)	
Data point term sent to Coder	System	15 Jan 2021 00:15:21
User entered 'Buspirone'	(b) (4), (b) (6)	15 Jan 2021 00:14:37

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:58
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	15 Jan 2021 00:14:37

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:58
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'worsening of ANXIETY' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	02 Mar 2021 22:35:33
	(b) (4)	
User entered 'anxiety'	(b) (4), (b) (6)	15 Jan 2021 00:14:37

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:58
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered '20'	(b) (4), (b) (6)	15 Jan 2021 00:14:37

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:58
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Jan 2021 00:14:37

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:58
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Jan 2021 00:14:37

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:58
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'twice daily (BID)'	(b) (4), (b) (6)	15 Jan 2021 00:14:37

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:58
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Jan 2021 00:14:37

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:58
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Jan 2021 00:14:37

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:58
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Jan 2021 00:14:37

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:58
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ANXIETY should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 07:24:52
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ANXIETY should be recorded, and update con med indication or provide clarification. ' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	02 Mar 2021 22:35:38
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ANXIETY should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 13:40:24
User entered '17 Sep 2020'	(b) (4), (b) (6)	15 Jan 2021 00:14:37

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:58
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	15 Jan 2021 00:14:37

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:58
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Rachel Law (b) (4)	02 Apr 2021 19:56:11
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Jan 2021 00:14:37

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:58
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered '21 Mar 2021' reason for change: Data Entry Error	Rachel Law (b) (4)	02 Apr 2021 19:56:11
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Jan 2021 00:14:37

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:58
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	15 Jan 2021 00:14:37

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:58
User entered '2'	System	15 Jan 2021 00:14:37

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:58
User entered '1'	System	15 Jan 2021 00:14:37

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:58
User entered '804 (804)'	System	15 Jan 2021 00:14:37

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:02:06
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM HYDROBROMIDE, PRODUCTSYNONYM: CELEXA [CITALOPRAM HYDROBROMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 07:56:56
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 07:56:56
Data point term sent to Coder	System	02 Mar 2021 22:37:34
User entered 'Celexa'	Andryelle Toledo (b) (4)	02 Mar 2021 22:36:46

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:02:19
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:36:46
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:02:26
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered 'worsening of depression'	Andryelle Toledo (b) (4)	02 Mar 2021 22:36:46

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:12
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:02:28
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered '40'	Andryelle Toledo (b) (4)	02 Mar 2021 22:36:46
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:15
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 19:02:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:02:32
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'mg (mg)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:36:46
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:17
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:36:46
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:19
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'once daily (QD)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:36:46
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:24
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:36:46
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:27
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered 'Oral (ORAL)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:36:46

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:29
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:36:46
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:48

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:33
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered '10 Feb 2021'	Andryelle Toledo (b) (4)	02 Mar 2021 22:36:46
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:35
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 22:36:46

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:38
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Rachel Law (b) (4)	02 Apr 2021 19:53:56
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:36:46
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:39
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	02 Apr 2021 19:53:56
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	02 Apr 2021 19:53:19
User entered '21 Mar 2021' reason for change: Data Entry Error	Rachel Law (b) (4)	02 Apr 2021 19:53:19
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:36:46
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:41
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:36:46
	(b) (4)	

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:03
User entered '1'	System	02 Mar 2021 22:36:46

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:03
User entered '1'	System	02 Mar 2021 22:36:46

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:03
User entered '804 (804)'	System	02 Mar 2021 22:36:46

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:45
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: PAROXETINE HYDROCHLORIDE, PRODUCTSYNONYM: PAXIL [PAROXETINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 04:10:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 04:10:39
Data point term sent to Coder	System	02 Apr 2021 19:56:30
User entered 'Paxil'	Rachel Law (b) (4)	02 Apr 2021 19:55:34

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:48

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:48
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered 'No (N)'	Rachel Law (b) (4)	02 Apr 2021 19:55:34

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered 'worsening of depression'	Rachel Law (b) (4)	02 Apr 2021 19:55:34

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:48

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered '20'	Rachel Law (b) (4)	02 Apr 2021 19:55:34

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:01
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered 'mg (mg)'	Rachel Law (b) (4)	02 Apr 2021 19:55:34

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:48

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:03
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered empty.	Rachel Law (b) (4)	02 Apr 2021 19:55:34

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:48

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:05
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered 'once daily (QD)'	Rachel Law (b) (4)	02 Apr 2021 19:55:34

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:07
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered empty.	Rachel Law (b) (4)	02 Apr 2021 19:55:34

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:48

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:09
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered 'Oral (ORAL)'	Rachel Law (b) (4)	02 Apr 2021 19:55:34

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:48

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:11
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered empty.	Rachel Law (b) (4)	02 Apr 2021 19:55:34

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered '22 Mar 2021'	Rachel Law (b) (4)	02 Apr 2021 19:55:34

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:16
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered '0'	Rachel Law (b) (4)	02 Apr 2021 19:55:34

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:19
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered 'Yes (Y)'	Rachel Law (b) (4)	02 Apr 2021 19:55:34

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:21
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered empty.	Rachel Law (b) (4)	02 Apr 2021 19:55:34

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:24
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered 'No (N)'	Rachel Law (b) (4)	02 Apr 2021 19:55:34

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 19:55:34

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 19:55:34

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Apr 2021 19:55:34

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:35
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Apr 2021 19:58:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Apr 2021 19:58:57
Data point term sent to Coder	System	02 Apr 2021 19:57:30
User entered 'buspirone'	Rachel Law (b) (4) (b) (4)	02 Apr 2021 19:57:13

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:48

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:36
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered 'No (N)'	Rachel Law (b) (4)	02 Apr 2021 19:57:13

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:39
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered 'worsening of anxiety'	Rachel Law (b) (4)	02 Apr 2021 19:57:13

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:48

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:40
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered '30'	Rachel Law (b) (4)	02 Apr 2021 19:57:13

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:42
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered 'mg (mg)'	Rachel Law (b) (4)	02 Apr 2021 19:57:13

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:48

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:45
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered empty.	Rachel Law (b) (4)	02 Apr 2021 19:57:13

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:48

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:47
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered 'twice daily (BID)'	Rachel Law (b) (4)	02 Apr 2021 19:57:13

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:48

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:49
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered empty.	Rachel Law (b) (4)	02 Apr 2021 19:57:13

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:48

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:51
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered 'Oral (ORAL)'	Rachel Law (b) (4)	02 Apr 2021 19:57:13

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:48

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered empty.	Rachel Law (b) (4)	02 Apr 2021 19:57:13

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:56
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered '22 Mar 2021'	Rachel Law (b) (4)	02 Apr 2021 19:57:13

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered '0'	Rachel Law (b) (4)	02 Apr 2021 19:57:13

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:05:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered 'Yes (Y)'	Rachel Law (b) (4)	02 Apr 2021 19:57:13

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:05:05
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered empty.	Rachel Law (b) (4)	02 Apr 2021 19:57:13

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:05:17
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered 'No (N)'	Rachel Law (b) (4)	02 Apr 2021 19:57:13

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Apr 2021 19:57:13

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 19:57:13

US3892054

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Apr 2021 19:57:13

US3892054

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:23:48

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:30:18
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Oct 2020 21:56:12
	(b) (4)	

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'USA-US209-2021-MRNA-1273-P301000004'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'Yes (Y)'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'No (N)'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'No (N)'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'Yes (Y)'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'No (N)'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'No (N)'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'No (N)'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'Michael'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'Adams'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered '5251 S Green St'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'Murray'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'UT'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered '84123'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'US'	System	05 Apr 2021 15:20:19

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Apr 2021 16:55:45
User entered '1'	System	05 Apr 2021 15:20:19

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'USA-US209-2021-MRNA-1273-P301000004'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'Yes (Y)'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'No (N)'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'No (N)'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'Yes (Y)'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'No (N)'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'No (N)'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'No (N)'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'Michael'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'Adams'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered '5251 S Green St'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'Murray'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'UT'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered '84123'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'US'	System	05 Apr 2021 15:20:19

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Apr 2021 16:55:45
User entered '1'	System	05 Apr 2021 15:20:19

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:23:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
User entered '05/Apr/2021 11:20'	(b) (4) System	05 Apr 2021 15:20:19

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:23:48

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered '1'	(b) (4), (b) (6)	05 Apr 2021 15:20:19

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'USA-US209-2021-MRNA-1273-P301000004'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'Yes (Y)'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'No (N)'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'No (N)'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'Yes (Y)'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'No (N)'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'No (N)'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'No (N)'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'Michael'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'Adams'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered '5251 S Green St'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'Murray'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'UT'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered '84123'	System	05 Apr 2021 15:12:06

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:55:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:27:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:24
User entered 'US'	System	05 Apr 2021 15:20:19

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Apr 2021 16:55:45
User entered '1'	System	05 Apr 2021 15:20:19

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:23:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
User entered '16/Apr/2021 11:55'	(b) (4) System	16 Apr 2021 16:55:45

US3892054

Folder: SAE USA-US209-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:23:48

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.	Michael Adams (b) (4)	19 Apr 2021 16:03:28
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:55:45