

US3172040 (Prod: Suncoast Research Group LLC - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:36:21

All time stamps listed in this document are displayed in GMT

US3172040

Form: Participant Creation

Data signed: (b) (4) 16 Feb 2021 15:05:28

Generated On: 09 Jun 2021 15:36:21

Participant ID

US3172040

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

US3172040

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

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

Visit date (dd MMM yyyy)	11 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3172040

Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Date of Birth (MMM yyyy)	(b) (6) 1943
Age	77
Age Units	YEARS
Age (Derived)	77
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Date of Informed Consent (*dd MMM yyyy*) 11 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input 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

US3172040

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Did the participant meet all eligibility criteria?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 16 Feb 2021 15:05:29

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Condition	LEFT EYE BLINDNESS
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3172040

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Condition	PRESBYOPIA
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Condition	BRUISING RIGHT ARM
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172040

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1988
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 1988
Start Year (derived)	1988
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Condition	PREVIOUS CATHERIZATION OF A STENT PLACEMENT
Start date (dd MMM yyyy)	UN UNK 1988
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1988
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1988
Start Year (derived)	1988
Stop Month and Year (derived)	JAN 1988
Stop Year (derived)	1988

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN UNK 1988
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 1988
Start Year (derived)	1988
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Condition	GOUT BIG TOE RIGHT
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 (9)

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Condition	SKIN TEAR LEFT ELBOW
Start date (dd MMM yyyy)	08 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Condition	LEFT EYE RETINAL DETACHMENT
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

US3172040

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	10:28 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 10:28
Height (xxx.x)	162.8 cm
Weight (xxx.x)	71.3 kg
BMI (xxx.x)	26.90176 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	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) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

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: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 15:05:29

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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) 16 Feb 2021 15:05:29

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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)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

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

Visit date (dd MMM yyyy)	11 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

What was the date of randomization? (dd MMM yyyy) 11 AUG 2020

What was the participant's randomization number? 185185

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

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) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

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)	11 AUG 2020
Time of assessment (00:00-23:59)	10:28 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 10:28
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	163 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

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)	11 AUG 2020
Time of assessment (00:00-23:59)	14:38 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 14:38
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	178 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

US3172040

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 AUG 2020

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

US3172040

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

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) 11 AUG 2020

What was the treatment time? (00:00-23:59) 14:08 (24 HR)

Treatment Date and Time (derived) 11 AUG 2020 14:08

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) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

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

Collection date (dd MMM yyyy)	11 AUG 2020
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Collection time (00:00-23:59)	12:57 (24 HR)
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Collection date and time (derived)	11 AUG 2020 12:57
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US3172040

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Collection date (dd MMM yyyy)			11 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:52	11 AUG 2020 12:52
Nasopharyngeal Swab 2	No		

US3172040

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 14:46

PC Open Date & Time

11 AUG 2020 14:28

PC Close Date & Time

11 AUG 2020 16:58

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

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 97.3 °F

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

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

PC Time Stamp	11 AUG 2020 18:00
PC Open Date & Time	11 AUG 2020 17:53
PC Close Date & Time	12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:21

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

97.8 °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

12 AUG 2020 14:16

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:21

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

98.4 °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

13 AUG 2020 12:01

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 14:26

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

15 AUG 2020 18:40

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

16 AUG 2020 16:34

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

17 AUG 2020 20:26

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

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

11 AUG 2020 14:47

PC Open Date & Time

11 AUG 2020 14:28

PC Close Date & Time

11 AUG 2020 16:58

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

11 AUG 2020 17:53

PC Close Date & Time

12 AUG 2020 11:59

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 14:17

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 12:01

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 14:27

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:21

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

15 AUG 2020 18:40

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 16:34

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:21

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

17 AUG 2020 20:27

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 14:48
PC Open Date & Time	11 AUG 2020 14:28
PC Close Date & Time	11 AUG 2020 16:58

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

11 AUG 2020 17:53

PC Close Date & Time

12 AUG 2020 11:59

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:21

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:21

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 14:17
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:21

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 ☒

PRODUCTION RELEASE (v12.003

54 of 1872

EAB) (1725)

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:21

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 12:02
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 1872

EAB) (1725)

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:21

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 14:27
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

58 of 1872

EAB) (1725)

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:21

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 18:40
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:21

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

60 of 1872

EAB) (1725)

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:21

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 16:34
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:21

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

62 of 1872

EAB) (1725)

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:21

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 20:27
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3172040

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 20 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3172040

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172040

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3172040

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172040

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 03 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3172040

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172040

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 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	VISIT2

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

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)	8 SEP 2020
Time of assessment (00:00-23:59)	09:40 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 09:40
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

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)	8 SEP 2020
Time of assessment (00:00-23:59)	12:03 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 12:03
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3172040

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 SEP 2020

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

US3172040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

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) 8 SEP 2020

What was the treatment time? (00:00-23:59) 11:33 (24 HR)

Treatment Date and Time (derived) 8 SEP 2020 11:33

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

US3172040

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

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

Collection date (dd MMM yyyy)	8 SEP 2020
-------------------------------	------------

Collection time (00:00-23:59)	11:02 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	8 SEP 2020 11:02
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US3172040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Collection date (dd MMM yyyy)			8 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:01	8 SEP 2020 11:01
Nasopharyngeal Swab 2	No		

US3172040

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

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

98.1 °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

08 SEP 2020 13:46

PC Open Date & Time

08 SEP 2020 11:53

PC Close Date & Time

08 SEP 2020 14:23

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

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 97.1 °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	08 SEP 2020 19:22
PC Open Date & Time	08 SEP 2020 15:18
PC Close Date & Time	09 SEP 2020 11:59

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:21

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

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:21

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

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:21

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.

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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

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:21

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

08 SEP 2020 11:53

PC Close Date & Time

08 SEP 2020 14:23

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 19:24

PC Open Date & Time

08 SEP 2020 15:18

PC Close Date & Time

09 SEP 2020 11:59

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:21

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

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:21

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

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:21

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

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 13:44
PC Open Date & Time	08 SEP 2020 11:53
PC Close Date & Time	08 SEP 2020 14:23

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 19:27
PC Open Date & Time	08 SEP 2020 15:18
PC Close Date & Time	09 SEP 2020 11:59

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:21

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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Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:21

Yes ☐

PC Time stamp

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:21

Yes ☐

PC Time stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:21

Yes ☐

PC Time stamp

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:21

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: 09 Jun 2021 15:36:21

Yes ☐

PC Time stamp

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:21

Yes ☐

PC Time stamp

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:21

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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Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:21

Yes ☐

PC Time stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3172040

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3172040

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3172040

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172040

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3172040

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172040

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 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

US3172040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	6 OCT 2020
Time of assessment (00:00-23:59)	09:00 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 09:00
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172040

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

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.

US3172040

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

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

Collection date (dd MMM yyyy)	6 OCT 2020
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Collection time (00:00-23:59)	09:38 (24 HR)
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Collection date and time (derived)	6 OCT 2020 09:38
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US3172040

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="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"/>

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="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"/>

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

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

Date and time of submission

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 103

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

19 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

26 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 117

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

03 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Date and time of submission	
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 138

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

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

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

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

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

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

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

31 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 152

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

07 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 159

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 166

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 173

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

28 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

04 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 187

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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"/>

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Close Date & Time](#)

22 FEB 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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"/>

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

25 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 208

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

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

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

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

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

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

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

04 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

11 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

18 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

25 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 <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"/>

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 243

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

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

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

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

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

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

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 250

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

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

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

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

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

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

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 APR 2021 00:01
Patient Cloud Close Date & Time	26 APR 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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"/>

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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"/>

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 JUL 2021 00:01
Patient Cloud Close Date & Time	05 JUL 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 JUL 2021 00:01
Patient Cloud Close Date & Time	02 AUG 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Patient Cloud Open Date & Time	26 AUG 2021 00:01
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Patient Cloud Close Date & Time	30 AUG 2021 23:59
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US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 404

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

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

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

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

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 SEP 2021 00:01
Patient Cloud Close Date & Time	20 SEP 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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="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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="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"/>

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 <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"/>

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 453

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

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

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

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

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

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

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 NOV 2021 00:01
Patient Cloud Close Date & Time	15 NOV 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 FEB 2022 00:01
Patient Cloud Close Date & Time	07 FEB 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 MAR 2022 00:01
Patient Cloud Close Date & Time	14 MAR 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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"/>

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 JUN 2022 00:01
Patient Cloud Close Date & Time	06 JUN 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 JUL 2022 00:01
Patient Cloud Close Date & Time	11 JUL 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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="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"/>

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Patient Cloud Open Date & Time	11 AUG 2022 00:01
Patient Cloud Close Date & Time	15 AUG 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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"/>

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Patient Cloud Open Date & Time	25 AUG 2022 00:01
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Patient Cloud Close Date & Time	29 AUG 2022 23:59
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US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 SEP 2022 00:01
Patient Cloud Close Date & Time	05 SEP 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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 ☐

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

DAY 796

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

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

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

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

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

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

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

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

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3172040

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:36:21

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

US3172040

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3172040

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172040

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:05:28

Generated On: 09 Jun 2021 15:36:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 07 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3172040

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:05:28

Generated On: 09 Jun 2021 15:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172040

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:05:28

Generated On: 09 Jun 2021 15:36:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 07 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3172040

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:05:28

Generated On: 09 Jun 2021 15:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172040

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3172040

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:05:29

Generated On: 09 Jun 2021 15:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172040

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 20:08:37

Generated On: 09 Jun 2021 15:36:21

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

Visit date (dd MMM yyyy)	12 MAR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3172040

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Apr 2021 15:56:30

Generated On: 09 Jun 2021 15:36:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 MAR 2021
Time of assessment (00:00-23:59)	07:40 (24 HR)
Vital Signs Date and Time (derived)	12 MAR 2021 07:40
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	157 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172040

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 20:08:37

Generated On: 09 Jun 2021 15:36:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 MAR 2021

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

US3172040

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 20:08:37

Generated On: 09 Jun 2021 15:36:21

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

Collection date (dd MMM yyyy)	12 MAR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	08:56 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	12 MAR 2021 08:56
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US3172040

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 20:08:37

Generated On: 09 Jun 2021 15:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172040

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 15:56:30

Generated On: 09 Jun 2021 15:36:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 06 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3172040

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 15:56:30

Generated On: 09 Jun 2021 15:36:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172040

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

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

US3172040

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3172040

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:36:21

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"/>

US3172040

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:36:21

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3172040

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

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:05:28

Generated On: 09 Jun 2021 15:36:21

Was this visit performed? Yes ☒
No ☐

Visit date (dd MMM yyyy) 25 JAN 2021

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

Folder OID UNBLND_DECIDE

US3172040

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 15:56:30

Generated On: 09 Jun 2021 15:36:21

Date of updated informed consent (dd MMM yyyy) 06 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) 25 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 _____

US3172040

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 15:05:28

Generated On: 09 Jun 2021 15:36:21

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

Collection date (dd MMM yyyy)	25 JAN 2021
-------------------------------	-------------

Collection time (00:00-23:59)	11:00 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	25 JAN 2021 11:00
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US3172040

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Feb 2021 15:05:28

Generated On: 09 Jun 2021 15:36:21

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

Collection date (dd MMM yyyy)	25 JAN 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	11:01
---------------------------------	-------

Collection Date and Time (derived)	25 JAN 2021 11:01
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US3172040

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Mar 2021 17:56:15

Generated On: 09 Jun 2021 15:36:21

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Mar 2021 17:56:15

Generated On: 09 Jun 2021 15:36:21

AEID	USA-US118-2021-MRNA-1273-P30 1000010
Adverse event	ACUTE EXACERBATION OF GOUT
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)	21 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)	22 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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)	21 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	22 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Mar 2021 17:56:15

Generated On: 09 Jun 2021 15:36:21

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

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Mar 2021 17:56:15

Generated On: 09 Jun 2021 15:36:21

SUBJECT CAME TODAY FOR
VISIT 209 AS PER PROTOCOL.
HE REPORTED BEEN ADMITTED
TO MERCY HOSPITAL ON
21FEB2020 AT 7:00 PM DUE TO
ACUTE EXACERBATION OF
GOUT, MANIFESTED WITH
SEVERE JOINT PAIN IN THE
RIGHT HAND POINTED FINGER
(TUBERELE OF TRAPEZIUM
AND RIGHT BIG TOE). TODAY
SUBJECT IS ASYMPTOMATIC
AND DENIES ANY SYMPTOMS
OR PAIN AT TIME OF VISIT. WE
WILL REQUEST MEDICAL
RECORDS AND UPDATE SAE
WHEN DOCUMENTS ARE
RECEIVED.

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

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Feb 2021 15:05:28

Generated On: 09 Jun 2021 15:36:21

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

Yes ☒

No ☐

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

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Mar 2021 17:56:15

Generated On: 09 Jun 2021 15:36:21

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Mar 2021 17:56:15

Generated On: 09 Jun 2021 15:36:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Mar 2021 17:56:15

Generated On: 09 Jun 2021 15:36:21

Name of Medication ESATALOPRAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Mar 2021 17:56:15

Generated On: 09 Jun 2021 15:36:21

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2003	
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"/>

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Mar 2021 17:56:15

Generated On: 09 Jun 2021 15:36:21

Name of Medication COLCHICINE

Prophylaxis Yes ☐
No ☒

Indication GOUT

Dose per administration 0.6

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)

364 of 1872

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Mar 2021 17:56:15

Generated On: 09 Jun 2021 15:36:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
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"/>

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Mar 2021 17:56:15

Generated On: 09 Jun 2021 15:36:21

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication PAIN FROM GOUT EXCESS

Dose per administration 800

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)

366 of 1872

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Mar 2021 17:56:15

Generated On: 09 Jun 2021 15:36:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3172040

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Feb 2021 15:05:28

Generated On: 09 Jun 2021 15:36:21

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3172040

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:36:21

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

US3172040

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:36:21

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 16 Mar 2021 17:56:15

Generated On: 09 Jun 2021 15:36:21

SAEID	USA-US118-2021-MRNA-1273-P301000010
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Mar 2021 17:56:15

Generated On: 09 Jun 2021 15:36:21

SAEID	USA-US118-2021-MRNA-1273-P301000010
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	15/MAR/2021 10:42
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

US3172040 (Prod: Suncoast Research Group LLC - ERN-PPDS)

US3172040

Form: Participant Creation

Generated On: 09 Jun 2021 15:36:21

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'US3172040'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 15:54:23

US3172040

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:36:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 18:19:21

US3172040

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 15:54:24

US3172040

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:36:21

[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 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Aug 2020 18:19:21

US3172040

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:36:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered 'SCRN'	System	11 Aug 2020 18:19:21

US3172040

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:21

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered (b) (6) 1943'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 15:54:25

US3172040

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:21

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '77'	(b) (4), (b) (6)	11 Aug 2020 18:19:45

US3172040

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:21

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:54
User entered 'YEARS'	System	11 Aug 2020 18:19:45

US3172040

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:21

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:54
User entered '77'	System	11 Aug 2020 18:20:18

US3172040

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:21

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Male (M)'	(b) (4), (b) (6)	11 Aug 2020 18:19:45

US3172040

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:21

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	11 Aug 2020 18:19:45

US3172040

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:21

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'I'	(b) (4), (b) (6)	11 Aug 2020 18:19:45

US3172040

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:21

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:19:45

US3172040

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:21

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:19:45

US3172040

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:21

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:19:45

US3172040

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:21

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:19:45

US3172040

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:19:45

US3172040

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:21

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:19:45

US3172040

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:21

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:19:45

US3172040

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:21

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:19:45

US3172040

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '11 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 18:20:18

US3172040

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:54
User entered 'Aug 2020'	System	11 Aug 2020 18:20:18

US3172040

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:54
User entered '2020'	System	11 Aug 2020 18:20:18

US3172040

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:21

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	11 Aug 2020 18:20:18

US3172040

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 18:20:18

US3172040

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:20:18

US3172040

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:21

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:20:18

US3172040

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:21

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:20:18

US3172040

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:21

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 15:54:24

US3172040

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:21

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:54
User entered 'I'	System	11 Aug 2020 18:22:25

US3172040

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 18:22:25

US3172040

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:36:21

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:20:31

US3172040

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual impairment and blindness (excl colour blindness), PT: Blindness unilateral, LLT: Blind left eye - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 08:35:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 08:35:25
Data point term sent to Coder	System	11 Aug 2020 19:23:36
User entered 'Left eye blindness'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:23:00

US3172040

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'UN UNK 2010'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:23:00

US3172040

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:23:00

US3172040

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	15 Sep 2020 20:55:27
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:23:00

US3172040

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User closed query 'Per DM CLR: Please review the stop date of this Chronic MH condition, as this condition is not expected to resolve. Please review and update stop date if appropriate or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 17:26:10
Query 'Per DM CLR: Please review the stop date of this Chronic MH condition, as this condition is not expected to resolve. Please review and update stop date if appropriate or provide explanation. ' answered with 'Data updated' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	15 Sep 2020 20:55:45
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	15 Sep 2020 20:55:27
User opened query 'Per DM CLR: Please review the stop date of this Chronic MH condition, as this condition is not expected to resolve. Please review and update stop date if appropriate or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 11:54:10
User entered 'UN UNK 2010'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:23:00

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:23:00

US3172040

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered 'Jan 2010'	System	11 Aug 2020 19:23:00

US3172040

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered '2010'	System	11 Aug 2020 19:23:00

US3172040

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered empty.	System	15 Sep 2020 20:55:27
User entered 'Jan 2010'	System	11 Aug 2020 19:23:00

US3172040

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered empty.	System	15 Sep 2020 20:55:27
User entered '2010'	System	11 Aug 2020 19:23:00

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Presbyopia, LLT: Presbyopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:24:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:24:18
Data point term sent to Coder	System	11 Aug 2020 19:23:36
User entered 'Presbyopia'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:23:19

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'UN UNK 2010'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:23:19

US3172040

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:23:19

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:23:19

US3172040

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:23:19

US3172040

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:23:19

US3172040

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered 'Jan 2010'	System	11 Aug 2020 19:23:19

US3172040

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered '2010'	System	11 Aug 2020 19:23:19

US3172040

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered empty.	System	11 Aug 2020 19:23:19

US3172040

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered empty.	System	11 Aug 2020 19:23:19

US3172040

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User closed query 'Per DM CLR: Please specify the location of Bruising. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 17:27:10
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Contusion, LLT: Bruising of arm - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 07:32:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 07:32:51
Query 'Per DM CLR: Please specify the location of Bruising. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'Data updated' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	15 Sep 2020 20:58:09
Data point term sent to Coder	System	15 Sep 2020 20:58:05
Coding entries removed.	Mariete Rendon (b) (4) (b) (4)	15 Sep 2020 20:57:58
User entered 'BRUISING Right arm' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	15 Sep 2020 20:57:58
User opened query 'Per DM CLR: Please specify the location of Bruising. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 13:30:46
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Contusion, LLT: Bruising - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:55:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:55:33
Data point term sent to Coder	System	31 Aug 2020 20:55:00

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:21

[Condition](#)

Audit	User	Time (GMT)
User entered 'BRUISING' reason for change: Data Entry Error	Mariete Rendon (b) (4)	31 Aug 2020 20:54:32
Data point term sent to Coder	(b) (4)	
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	System	31 Aug 2020 15:58:51
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' answered with 'This has been updated. ' (Site from System).	System	31 Aug 2020 15:58:35
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' answered with 'This has been updated. ' (Site from System).	Jessie Downs (b) (4)	31 Aug 2020 15:58:35
User entered 'BLEEDING PROBLEMS' reason for change: Data Entry Error	(b) (4)	
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	Jessie Downs (b) (4)	31 Aug 2020 15:58:04
Data point term sent to Coder	Coder Import (b) (4)	12 Aug 2020 23:40:08
User entered 'Bleeding Problems/Bruising'	(b) (4)	
	System	11 Aug 2020 19:24:37
	Mariete Rendon (b) (4)	11 Aug 2020 19:24:03
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'UN UNK 2008'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:24:03

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:24:03

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:24:03

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:24:03

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:24:03

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered 'Jan 2008'	System	11 Aug 2020 19:24:03

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered '2008'	System	11 Aug 2020 19:24:03

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered empty.	System	11 Aug 2020 19:24:03

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered empty.	System	11 Aug 2020 19:24:03

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:36:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 17:28:30
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'Data updated' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	15 Sep 2020 20:59:23
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 11:55:51
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:25:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:25:21
Data point term sent to Coder	System	11 Aug 2020 19:24:37
User entered 'Hypertension'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:24:24

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'UN UNK 1988'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:24:24

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:36:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:24:24

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:36:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:24:24

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:24:24

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:36:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:24:24

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered 'Jan 1988'	System	11 Aug 2020 19:24:24

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered '1988'	System	11 Aug 2020 19:24:24

US3172040

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered empty.	System	11 Aug 2020 19:24:24

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered empty.	System	11 Aug 2020 19:24:24

US3172040

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:36:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User coded data point as SOC: Surgical and medical procedures, HLT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Stent placement, LLT: Stent placement - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 08:16:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 08:16:12
User closed query 'Per DM CLR: Please specify location of PREVIOUS CATHERIZATION OF A STENT PLACEMENT. Update MH term as appropriate.	(b) (4), (b) (6)	21 Sep 2020 17:29:18
' (Site from DM).		
Query 'Per DM CLR: Please specify location of PREVIOUS CATHERIZATION OF A STENT PLACEMENT. Update MH term as appropriate.	Mariete Rendon (b) (4) (b) (4)	15 Sep 2020 21:00:22
' answered with 'Unknown location' (Site from DM).		
User opened query 'Per DM CLR: Please specify location of PREVIOUS CATHERIZATION OF A STENT PLACEMENT. Update MH term as appropriate.	(b) (4), (b) (6)	04 Sep 2020 11:54:44
' (Site from DM).		
Data point term sent to Coder	System	11 Aug 2020 19:25:38
User entered 'Previous catherization of a stent placement'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:25:12

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'UN UNK 1988'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:25:12

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:36:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:25:12

US3172040

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:36:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:25:12

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'UN UNK 1988'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:25:12

US3172040

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:36:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:25:12

US3172040

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered 'Jan 1988'	System	11 Aug 2020 19:25:12

US3172040

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered '1988'	System	11 Aug 2020 19:25:12

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered 'Jan 1988'	System	11 Aug 2020 19:25:12

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered '1988'	System	11 Aug 2020 19:25:12

US3172040

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:36:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:27:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:27:14
Data point term sent to Coder	System	11 Aug 2020 19:26:39
User entered 'Coronary Artery Disease'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:25:40

US3172040

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'UN UNK 1988'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:25:40

US3172040

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:36:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:25:40

US3172040

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:36:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:25:40

US3172040

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:25:40

US3172040

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:36:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:25:40

US3172040

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered 'Jan 1988'	System	11 Aug 2020 19:25:40

US3172040

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered '1988'	System	11 Aug 2020 19:25:40

US3172040

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered empty.	System	11 Aug 2020 19:25:40

US3172040

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered empty.	System	11 Aug 2020 19:25:40

US3172040

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:36:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Podagra - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 20:10:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 20:10:49
User closed query 'Per DM CLR RQ: Response to previous query noted. However, please also indicate the laterality of the GOUT BIG TOE (i.e. right, left, bilateral toes). Please update MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:47:41
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 00:47:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 00:47:24
Data point term sent to Coder	System	22 Oct 2020 20:00:13
Query 'Per DM CLR RQ: Response to previous query noted. However, please also indicate the laterality of the GOUT BIG TOE (i.e. right, left, bilateral toes). Please update MH eCRF as appropriate.' answered with 'data updated' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 19:59:27
Coding entries removed.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 19:59:18
User entered 'GOUT BIG TOE right' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 19:59:18
User opened query 'Per DM CLR RQ: Response to previous query noted. However, please also indicate the laterality of the GOUT BIG TOE (i.e. right, left, bilateral toes). Please update MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 10:32:07

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Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:36:21

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the location of GOUT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 17:29:46
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 13:51:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 13:51:41
Data point term sent to Coder	System	15 Sep 2020 21:02:12
Query 'Per DM CLR: Please specify the location of GOUT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding ConMed entries, if applicable.	Mariete Rendon (b) (4) (b) (4)	15 Sep 2020 21:01:37
' answered with 'Data updated' (Site from DM).		
Coding entries removed.	Mariete Rendon (b) (4) (b) (4)	15 Sep 2020 21:01:12
User entered 'GOUT big toe' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	15 Sep 2020 21:01:12
User opened query 'Per DM CLR: Please specify the location of GOUT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding ConMed entries, if applicable.	(b) (4), (b) (6)	04 Sep 2020 11:55:09
' (Site from DM).		
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:27:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:27:15
Data point term sent to Coder	System	11 Aug 2020 19:26:39
User entered 'Gout'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:25:55

US3172040

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'UN UNK 2009'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:25:55

US3172040

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:36:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:25:55

US3172040

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:36:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:25:55

US3172040

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:25:55

US3172040

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:36:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:25:55

US3172040

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered 'Jan 2009'	System	11 Aug 2020 19:25:55

US3172040

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered '2009'	System	11 Aug 2020 19:25:55

US3172040

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered empty.	System	11 Aug 2020 19:25:55

US3172040

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered empty.	System	11 Aug 2020 19:25:55

US3172040

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:36:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Skin laceration, LLT: Skin tear - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 11:02:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 11:02:23
Data point term sent to Coder	System	11 Aug 2020 19:26:42
User entered 'Skin tear left elbow'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:26:26

US3172040

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '08 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:26:26

US3172040

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:36:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:26:26

US3172040

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:36:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:26:26

US3172040

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:26:26

US3172040

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:36:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:26:26

US3172040

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered 'Aug 2020'	System	11 Aug 2020 19:26:26

US3172040

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered '2020'	System	11 Aug 2020 19:26:26

US3172040

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered empty.	System	11 Aug 2020 19:26:26

US3172040

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered empty.	System	11 Aug 2020 19:26:26

US3172040

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:36:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:27:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:27:15
Data point term sent to Coder	System	11 Aug 2020 19:26:42
User entered 'Anxiety'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:26:41

US3172040

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'UN UNK 2003'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:26:41

US3172040

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:36:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:26:41

US3172040

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:36:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:26:41

US3172040

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:26:41

US3172040

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:36:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:26:41

US3172040

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered 'Jan 2003'	System	11 Aug 2020 19:26:41

US3172040

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered '2003'	System	11 Aug 2020 19:26:41

US3172040

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered empty.	System	11 Aug 2020 19:26:41

US3172040

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered empty.	System	11 Aug 2020 19:26:41

US3172040

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:36:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
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) (b) (4)	11 Aug 2020 19:28:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:28:18
Data point term sent to Coder	System	11 Aug 2020 19:27:42
User entered 'Depression'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:26:57

US3172040

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'UN UNK 2003'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:26:57

US3172040

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:36:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:26:57

US3172040

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:36:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:26:57

US3172040

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:26:57

US3172040

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:36:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:26:57

US3172040

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered 'Jan 2003'	System	11 Aug 2020 19:26:57

US3172040

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered '2003'	System	11 Aug 2020 19:26:57

US3172040

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered empty.	System	11 Aug 2020 19:26:57

US3172040

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered empty.	System	11 Aug 2020 19:26:57

US3172040

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:36:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User coded data point as SOC: Eye disorders, HLGT: Ocular structural change, deposit and degeneration NEC, HLT: Retinal structural change, deposit and degeneration, PT: Retinal detachment, LLT: Retinal detachment - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:28:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:28:18
Data point term sent to Coder	System	11 Aug 2020 19:27:42
User entered 'Left eye retinal detachment'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:27:22

US3172040

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'un UNK 2010'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:27:22

US3172040

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:36:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:27:22

US3172040

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:36:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:27:22

US3172040

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'un UNK 2010'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:27:22

US3172040

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:36:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:27:22

US3172040

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered 'Jan 2010'	System	11 Aug 2020 19:27:22

US3172040

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered '2010'	System	11 Aug 2020 19:27:22

US3172040

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered 'Jan 2010'	System	11 Aug 2020 19:27:22

US3172040

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered '2010'	System	11 Aug 2020 19:27:22

US3172040

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:18:16

US3172040

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '11 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:18:16

US3172040

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '10:28'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:18:16

US3172040

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered '11 Aug 2020 10:28'	System	11 Aug 2020 19:18:16

US3172040

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '162.8' cm	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:18:16
DataPoint set to visible.	System	11 Aug 2020 18:22:25

US3172040

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '71.3' kg	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:18:16
DataPoint set to visible.	System	11 Aug 2020 18:22:25

US3172040

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
Amendment Manager: User entered '26.90176'	System	16 Sep 2020 23:51:41
User entered '26.9'	System	11 Aug 2020 19:18:16
DataPoint set to visible.	System	11 Aug 2020 18:22:25

US3172040

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered 'kg/m2'	System	11 Aug 2020 19:18:16
DataPoint set to visible.	System	11 Aug 2020 18:22:25

US3172040

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:18:16

US3172040

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 13:21:09
Query 'Data is required. Please provide.' answered with 'PER GUIDELINES, ND' (Site from System).	Mariete Rendon (b) (4) (b) (4)	28 Aug 2020 20:56:12
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 19:18:16
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:18:16

US3172040

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:18:16

US3172040

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:18:16

US3172040

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered 'bpm'	System	11 Aug 2020 19:18:16

US3172040

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:18:16

US3172040

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered 'breaths/min'	System	11 Aug 2020 19:18:16

US3172040

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:18:16

US3172040

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered 'mmHg'	System	11 Aug 2020 19:18:16

US3172040

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:18:16

US3172040

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered 'mmHg'	System	11 Aug 2020 19:18:16

US3172040

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55

US3172040

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55

US3172040

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:36:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	01 Oct 2020 21:53:39
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:18:53

US3172040

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:36:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	01 Oct 2020 21:53:39
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 11:20:13
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		08 Sep 2020 16:02:45
User entered '11 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:18:53

US3172040

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:21

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 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:19:28

US3172040

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:21

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 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:19:28

US3172040

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:21

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 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:19:28

US3172040

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:21

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 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:19:28

US3172040

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:21

[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 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:19:28

US3172040

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:21

[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 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:19:28

US3172040

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:21

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 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:19:28

US3172040

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:21

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 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:19:28

US3172040

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:21

[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 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:19:28

US3172040

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:21

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 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:19:28

US3172040

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:21

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 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:19:28

US3172040

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:21

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:19:28

US3172040

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:19:28

US3172040

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:21

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:19:28

US3172040

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:19:28

US3172040

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:21

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 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:19:28

US3172040

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:21

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 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:19:28

US3172040

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:21

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 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:19:28

US3172040

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:19:28

US3172040

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:21

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:19:28

US3172040

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:19:28

US3172040

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:36:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 18:28:35

US3172040

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '11 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 18:28:35

US3172040

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Aug 2020 18:28:35

US3172040

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:36:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'VISIT1'	System	11 Aug 2020 18:28:35

US3172040

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 15:59:47

US3172040

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:36:21

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:34:36
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:34:36
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 15:59:47
User entered '185185' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 15:59:47

US3172040

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 15:59:47

US3172040

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:36:21

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)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:28:53

US3172040

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:36:21

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)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:28:53

US3172040

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:28:53

US3172040

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:28:53

US3172040

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:36:21

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:28:53

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:36:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:36:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:36:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:36:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User accepted default value 'Pre-Dose (PREDOSE)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '11 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:05:30
	(b) (4)	
User entered '10:28'	Mariete Rendon (b) (4)	11 Aug 2020 19:29:35
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered '11 Aug 2020 10:28'	System	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '37.1' C	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '83'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'bpm'	System	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '16'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'breaths/min'	System	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 17:27:16
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'As per Sub-I this was considered not clinically significant. ' (Site from System).	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 14:07:08
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	11 Aug 2020 19:29:35
User entered '163'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'mmHg'	System	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '79'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'mmHg'	System	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:36:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:36:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User accepted default value 'Post-Dose (POSTDOSE)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '11 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	17 Aug 2020 17:12:48
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		11 Aug 2020 19:29:35
User entered '14:38'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered '11 Aug 2020 14:38'	System	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '37.1' C	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '82'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'bpm'	System	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '16'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'breaths/min'	System	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 17:27:49
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'As per Sub-I this was considered not clinically significant. ' (Site from System).	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 14:08:37
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	11 Aug 2020 19:29:35
User entered '178'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'mmHg'	System	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '94'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'mmHg'	System	11 Aug 2020 19:29:35

US3172040

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:36:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	01 Oct 2020 21:53:53
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:42

US3172040

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:36:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '11 Aug 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	01 Oct 2020 21:53:53
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:42

US3172040

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 18:29:29

US3172040

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:29:29

US3172040

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:21

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)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:05:30
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:29:29

US3172040

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 18:29:29

US3172040

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:05:30
	(b) (4)	
User entered '11 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 18:29:29

US3172040

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '14:08'	(b) (4), (b) (6)	11 Aug 2020 18:29:29

US3172040

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered '11 Aug 2020 14:08'	System	11 Aug 2020 18:29:29

US3172040

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	11 Aug 2020 18:29:29

US3172040

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'ONCE'	System	11 Aug 2020 18:29:29

US3172040

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:21

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 18:29:29

US3172040

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:57

US3172040

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '11 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:57

US3172040

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '12:57'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:29:57

US3172040

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered '11 Aug 2020 12:57'	System	11 Aug 2020 19:29:57

US3172040

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '11 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:30:15

US3172040

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:36:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:30:15

US3172040

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:36:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:30:15

US3172040

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:36:21

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:05:30
	(b) (4)	
User entered '12:52'	Mariete Rendon (b) (4)	11 Aug 2020 19:30:15
	(b) (4)	

US3172040

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered '11 Aug 2020 12:52'	System	11 Aug 2020 19:30:15

US3172040

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:36:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:30:15

US3172040

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:36:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	16 Sep 2020 18:30:55
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:30:15

US3172040

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:36:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	16 Sep 2020 18:30:55
User entered '12:52'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:30:15

US3172040

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered empty.	System	16 Sep 2020 18:30:55
User entered '11 Aug 2020 12:52'	System	11 Aug 2020 19:30:15

US3172040

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 19:30:22

US3172040

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'I'	System	11 Aug 2020 19:30:22

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-11T14:45:33', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '446a1857-f3bc-425c-a264-94bfbd2c6b0d' User entered 'Yes (Y)'	System	11 Aug 2020 18:46:13
	System	11 Aug 2020 18:46:13

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-11T14:46:01', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '446a1857-f3bc-425c-a264-94bfbd2c6b0d' User entered '98.8'	System	11 Aug 2020 18:46:13
	System	11 Aug 2020 18:46:13

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-11T14:46:07', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '446a1857-f3bc-425c-a264-94bfbd2c6b0d'	System	11 Aug 2020 18:46:13
User entered 'No (N)'	System	11 Aug 2020 18:46:13

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-11T14:46:11', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '446a1857-f3bc-425c-a264-94bfbd2c6b0d' User entered '11 Aug 2020 14:46'	System	11 Aug 2020 18:46:13
	System	11 Aug 2020 18:46:13

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '11 Aug 2020 14:28'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '11 Aug 2020 16:58'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-11T17:59:48', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'a0fc6839-bcb1-478f-bf4e-f590163252ff' User entered 'Yes (Y)'	System	11 Aug 2020 22:00:06
	System	11 Aug 2020 22:00:06

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-11T17:59:39', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'a0fc6839-bcb1-478f-bf4e-f590163252ff' User entered '97.3'	System	11 Aug 2020 22:00:06
	System	11 Aug 2020 22:00:06

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-11T17:56:18', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'a0fc6839-bcb1-478f-bf4e-f590163252ff' User entered 'No (N)'	System	11 Aug 2020 22:00:06
	System	11 Aug 2020 22:00:06

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-11T18:00:00', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'a0fc6839-bcb1-478f-bf4e-f590163252ff' User entered '11 Aug 2020 18:00'	System	11 Aug 2020 22:00:06
	System	11 Aug 2020 22:00:06

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '11 Aug 2020 17:53'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 2'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-12T14:16:33', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '9249b5a0-d641-49c7-ad5d-ac7b754b2182' User entered 'Yes (Y)'	System	12 Aug 2020 18:16:48
	System	12 Aug 2020 18:16:48

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-12T14:16:40', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '9249b5a0-d641-49c7-ad5d-ac7b754b2182' User entered '97.8'	System	12 Aug 2020 18:16:48
	System	12 Aug 2020 18:16:48

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-12T14:16:43', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '9249b5a0-d641-49c7-ad5d-ac7b754b2182'	System	12 Aug 2020 18:16:48
User entered 'No (N)'	System	12 Aug 2020 18:16:48

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-12T14:16:46', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '9249b5a0-d641-49c7-ad5d-ac7b754b2182'	System	12 Aug 2020 18:16:48
User entered '12 Aug 2020 14:16'	System	12 Aug 2020 18:16:48

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 3'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-13T12:01:14', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'e0ed3225-ef81-47ed-bbbd-1a4d74b24ae4' User entered 'Yes (Y)'	System	13 Aug 2020 16:01:29
	System	13 Aug 2020 16:01:29

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-13T12:01:19', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'e0ed3225-ef81-47ed-bbbd-1a4d74b24ae4' User entered '98.4'	System	13 Aug 2020 16:01:29
	System	13 Aug 2020 16:01:29

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-13T12:01:23', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'e0ed3225-ef81-47ed-bbbd-1a4d74b24ae4'	System	13 Aug 2020 16:01:29
User entered 'No (N)'	System	13 Aug 2020 16:01:29

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-13T12:01:25', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'e0ed3225-ef81-47ed-bbbd-1a4d74b24ae4' User entered '13 Aug 2020 12:01'	System	13 Aug 2020 16:01:29
	System	13 Aug 2020 16:01:29

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 4'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-14T14:26:41', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'b3621cf3-85a4-41c9-bfae-0e92c02d4939' User entered 'Yes (Y)'	System	14 Aug 2020 18:26:54
	System	14 Aug 2020 18:26:54

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-14T14:26:47', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'b3621cf3-85a4-41c9-bfae-0e92c02d4939' User entered '98.7'	System	14 Aug 2020 18:26:54
	System	14 Aug 2020 18:26:54

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-14T14:26:50', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'b3621cf3-85a4-41c9-bfae-0e92c02d4939'	System	14 Aug 2020 18:26:54
User entered 'No (N)'	System	14 Aug 2020 18:26:54

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-14T14:26:52', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'b3621cf3-85a4-41c9-bfae-0e92c02d4939'	System	14 Aug 2020 18:26:54
User entered '14 Aug 2020 14:26'	System	14 Aug 2020 18:26:54

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 5'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-15T18:39:53', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'e05fa52f-48d0-461d-9d5d-32b6b57fc12c' User entered 'Yes (Y)'	System	15 Aug 2020 22:40:10
	System	15 Aug 2020 22:40:10

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:21

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-15T18:39:58', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'e05fa52f-48d0-461d-9d5d-32b6b57fc12c' User entered '97.4'	System	15 Aug 2020 22:40:10
	System	15 Aug 2020 22:40:10

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-15T18:40:02', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'e05fa52f-48d0-461d-9d5d-32b6b57fc12c'	System	15 Aug 2020 22:40:10
User entered 'No (N)'	System	15 Aug 2020 22:40:10

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-15T18:40:07', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'e05fa52f-48d0-461d-9d5d-32b6b57fc12c'	System	15 Aug 2020 22:40:10
User entered '15 Aug 2020 18:40'	System	15 Aug 2020 22:40:10

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 6'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-16T16:34:13', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'e636e5da-60ee-4197-8b30-92b6a2eb4df5' User entered 'Yes (Y)'	System	16 Aug 2020 20:34:27
	System	16 Aug 2020 20:34:27

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-16T16:34:17', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'e636e5da-60ee-4197-8b30-92b6a2eb4df5' User entered '98.1'	System	16 Aug 2020 20:34:27
	System	16 Aug 2020 20:34:27

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-16T16:34:22', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'e636e5da-60ee-4197-8b30-92b6a2eb4df5'	System	16 Aug 2020 20:34:27
User entered 'No (N)'	System	16 Aug 2020 20:34:27

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-16T16:34:24', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'e636e5da-60ee-4197-8b30-92b6a2eb4df5'	System	16 Aug 2020 20:34:27
User entered '16 Aug 2020 16:34'	System	16 Aug 2020 20:34:27

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 7'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-17T20:26:36', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'ee2eb8ef-9668-497c-8a79-79b82274927b' User entered 'Yes (Y)'	System	18 Aug 2020 00:26:53
	System	18 Aug 2020 00:26:53

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-17T20:26:40', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'ee2eb8ef-9668-497c-8a79-79b82274927b' User entered '97.1'	System	18 Aug 2020 00:26:53
	System	18 Aug 2020 00:26:53

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-17T20:26:43', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'ee2eb8ef-9668-497c-8a79-79b82274927b' User entered 'No (N)'	System	18 Aug 2020 00:26:53
	System	18 Aug 2020 00:26:53

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-17T20:26:50', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'ee2eb8ef-9668-497c-8a79-79b82274927b' User entered '17 Aug 2020 20:26'	System	18 Aug 2020 00:26:53
	System	18 Aug 2020 00:26:53

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-11T14:47:10', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'e39e61b8-ab43-4ced-8b97-7bc9d9596ecd' User entered 'None (1)'	System	11 Aug 2020 18:47:55
	System	11 Aug 2020 18:47:55

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-11T14:47:13', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'e39e61b8-ab43-4ced-8b97-7bc9d9596ecd' User entered 'No (N)'	System	11 Aug 2020 18:47:55
	System	11 Aug 2020 18:47:55

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-11T14:47:17', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'e39e61b8-ab43-4ced-8b97-7bc9d9596ecd' User entered 'No (N)'	System	11 Aug 2020 18:47:55
	System	11 Aug 2020 18:47:55

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-11T14:47:49', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'e39e61b8-ab43-4ced-8b97-7bc9d9596ecd' User entered 'None (1)'	System	11 Aug 2020 18:47:55
	System	11 Aug 2020 18:47:55

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-11T14:47:51', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'e39e61b8-ab43-4ced-8b97-7bc9d9596ecd' User entered '11 Aug 2020 14:47'	System	11 Aug 2020 18:47:55
	System	11 Aug 2020 18:47:55

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '11 Aug 2020 14:28'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '11 Aug 2020 16:58'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '11 Aug 2020 17:53'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 2'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-12T14:16:53', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'e4f7f196-30b4-47f0-bbe4-443e71ff688a'	System	12 Aug 2020 18:17:05
User entered 'None (1)'	System	12 Aug 2020 18:17:05

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-12T14:16:56', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'e4f7f196-30b4-47f0-bbe4-443e71ff688a'	System	12 Aug 2020 18:17:05
User entered 'No (N)'	System	12 Aug 2020 18:17:05

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-12T14:16:59', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'e4f7f196-30b4-47f0-bbe4-443e71ff688a' User entered 'No (N)'	System	12 Aug 2020 18:17:05
	System	12 Aug 2020 18:17:05

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-12T14:17:01', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'e4f7f196-30b4-47f0-bbe4-443e71ff688a' User entered 'None (1)'	System	12 Aug 2020 18:17:05
	System	12 Aug 2020 18:17:05

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-12T14:17:03', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'e4f7f196-30b4-47f0-bbe4-443e71ff688a' User entered '12 Aug 2020 14:17'	System	12 Aug 2020 18:17:05
	System	12 Aug 2020 18:17:05

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 3'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-13T12:01:29', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'c964239a-b17d-4e09-b8e7-e73316d3e536' User entered 'None (1)'	System	13 Aug 2020 16:02:05
	System	13 Aug 2020 16:02:05

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-13T12:01:38', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'c964239a-b17d-4e09-b8e7-e73316d3e536'	System	13 Aug 2020 16:02:05
User entered 'No (N)'	System	13 Aug 2020 16:02:05

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-13T12:01:40', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'c964239a-b17d-4e09-b8e7-e73316d3e536' User entered 'No (N)'	System	13 Aug 2020 16:02:05
	System	13 Aug 2020 16:02:05

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-13T12:01:43', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'c964239a-b17d-4e09-b8e7-e73316d3e536' User entered 'None (1)'	System	13 Aug 2020 16:02:05
	System	13 Aug 2020 16:02:05

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-13T12:01:45', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'c964239a-b17d-4e09-b8e7-e73316d3e536' User entered '13 Aug 2020 12:01'	System	13 Aug 2020 16:02:05
	System	13 Aug 2020 16:02:05

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 4'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-14T14:26:56', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'ff8b025b-d4a1-44a4-9eb3-d9964b3a85f3'	System	14 Aug 2020 18:27:06
User entered 'None (1)'	System	14 Aug 2020 18:27:06

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-14T14:26:58', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'ff8b025b-d4a1-44a4-9eb3-d9964b3a85f3'	System	14 Aug 2020 18:27:06
User entered 'No (N)'	System	14 Aug 2020 18:27:06

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-14T14:27:00', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'ff8b025b-d4a1-44a4-9eb3-d9964b3a85f3' User entered 'No (N)'	System	14 Aug 2020 18:27:06
	System	14 Aug 2020 18:27:06

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-14T14:27:01', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'ff8b025b-d4a1-44a4-9eb3-d9964b3a85f3' User entered 'None (1)'	System	14 Aug 2020 18:27:06
	System	14 Aug 2020 18:27:06

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-14T14:27:03', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'ff8b025b-d4a1-44a4-9eb3-d9964b3a85f3' User entered '14 Aug 2020 14:27'	System	14 Aug 2020 18:27:06
	System	14 Aug 2020 18:27:06

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 5'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-15T18:40:11', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'ebe6d990-fc03-4d9c-8aed-7fc2ad66f0bf'	System	15 Aug 2020 22:40:20
User entered 'None (1)'	System	15 Aug 2020 22:40:20

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-15T18:40:13', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'ebe6d990-fc03-4d9c-8aed-7fc2ad66f0bf' User entered 'No (N)'	System	15 Aug 2020 22:40:20
	System	15 Aug 2020 22:40:20

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-15T18:40:14', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'ebe6d990-fc03-4d9c-8aed-7fc2ad66f0bf'	System	15 Aug 2020 22:40:20
User entered 'No (N)'	System	15 Aug 2020 22:40:20

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-15T18:40:16', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'ebe6d990-fc03-4d9c-8aed-7fc2ad66f0bf'	System	15 Aug 2020 22:40:20
User entered 'None (1)'	System	15 Aug 2020 22:40:20

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-15T18:40:18', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'ebe6d990-fc03-4d9c-8aed-7fc2ad66f0bf' User entered '15 Aug 2020 18:40'	System	15 Aug 2020 22:40:20
	System	15 Aug 2020 22:40:20

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 6'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-16T16:34:28', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'bfcf7ce7-8c74-4a60-8cbb-8b62b7a50bb9'	System	16 Aug 2020 20:34:37
User entered 'None (1)'	System	16 Aug 2020 20:34:37

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-16T16:34:29', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'bfcf7ce7-8c74-4a60-8cbb-8b62b7a50bb9'	System	16 Aug 2020 20:34:37
User entered 'No (N)'	System	16 Aug 2020 20:34:37

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-16T16:34:31', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'bfcf7ce7-8c74-4a60-8cbb-8b62b7a50bb9' User entered 'No (N)'	System	16 Aug 2020 20:34:37
	System	16 Aug 2020 20:34:37

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-16T16:34:32', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'bfcf7ce7-8c74-4a60-8cbb-8b62b7a50bb9'	System	16 Aug 2020 20:34:37
User entered 'None (1)'	System	16 Aug 2020 20:34:37

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-16T16:34:34', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'bfcf7ce7-8c74-4a60-8cbb-8b62b7a50bb9' User entered '16 Aug 2020 16:34'	System	16 Aug 2020 20:34:37
	System	16 Aug 2020 20:34:37

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 7'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-17T20:27:06', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '2b31e69d-37d1-4ad9-bfb0-150607f37c9d' User entered 'None (1)'	System	18 Aug 2020 00:27:21
	System	18 Aug 2020 00:27:21

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-17T20:27:09', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '2b31e69d-37d1-4ad9-bfb0-150607f37c9d' User entered 'No (N)'	System	18 Aug 2020 00:27:21
	System	18 Aug 2020 00:27:21

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-17T20:27:11', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '2b31e69d-37d1-4ad9-bfb0-150607f37c9d' User entered 'No (N)'	System	18 Aug 2020 00:27:21
	System	18 Aug 2020 00:27:21

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-17T20:27:14', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '2b31e69d-37d1-4ad9-bfb0-150607f37c9d' User entered 'None (1)'	System	18 Aug 2020 00:27:21
	System	18 Aug 2020 00:27:21

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-17T20:27:16', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '2b31e69d-37d1-4ad9-bfb0-150607f37c9d' User entered '17 Aug 2020 20:27'	System	18 Aug 2020 00:27:21
	System	18 Aug 2020 00:27:21

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-11T14:48:10', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '11a1d1b2-2592-4b49-ad45-084143786cae' User entered 'None (0)'	System	11 Aug 2020 18:48:29
	System	11 Aug 2020 18:48:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-11T14:48:12', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '11a1d1b2-2592-4b49-ad45-084143786cae' User entered 'None (0)'	System	11 Aug 2020 18:48:29
	System	11 Aug 2020 18:48:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-11T14:48:16', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '11a1d1b2-2592-4b49-ad45-084143786cae' User entered 'None (0)'	System	11 Aug 2020 18:48:29
	System	11 Aug 2020 18:48:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-11T14:48:19', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '11a1d1b2-2592-4b49-ad45-084143786cae' User entered 'None (0)'	System	11 Aug 2020 18:48:29
	System	11 Aug 2020 18:48:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-11T14:48:22', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '11a1d1b2-2592-4b49-ad45-084143786cae' User entered 'None (0)'	System	11 Aug 2020 18:48:29
	System	11 Aug 2020 18:48:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-11T14:48:24', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '11a1d1b2-2592-4b49-ad45-084143786cae' User entered 'None (0)'	System	11 Aug 2020 18:48:29
	System	11 Aug 2020 18:48:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-11T14:48:26', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '11a1d1b2-2592-4b49-ad45-084143786cae' User entered 'No (N)'	System	11 Aug 2020 18:48:29
	System	11 Aug 2020 18:48:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-11T14:48:27', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '11a1d1b2-2592-4b49-ad45-084143786cae' User entered '11 Aug 2020 14:48'	System	11 Aug 2020 18:48:29
	System	11 Aug 2020 18:48:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '11 Aug 2020 14:28'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '11 Aug 2020 16:58'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '11 Aug 2020 17:53'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 2'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-12T14:17:07', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'd326a08d-10ea-4a57-80e7-2958789f5647' User entered 'None (0)'	System	12 Aug 2020 18:17:24
	System	12 Aug 2020 18:17:24

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-12T14:17:09', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'd326a08d-10ea-4a57-80e7-2958789f5647' User entered 'None (0)'	System	12 Aug 2020 18:17:24
	System	12 Aug 2020 18:17:24

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-12T14:17:11', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'd326a08d-10ea-4a57-80e7-2958789f5647' User entered 'None (0)'	System	12 Aug 2020 18:17:24
	System	12 Aug 2020 18:17:24

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-12T14:17:13', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'd326a08d-10ea-4a57-80e7-2958789f5647' User entered 'None (0)'	System	12 Aug 2020 18:17:24
	System	12 Aug 2020 18:17:24

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-12T14:17:15', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'd326a08d-10ea-4a57-80e7-2958789f5647' User entered 'None (0)'	System	12 Aug 2020 18:17:24
	System	12 Aug 2020 18:17:24

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-12T14:17:17', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'd326a08d-10ea-4a57-80e7-2958789f5647' User entered 'None (0)'	System	12 Aug 2020 18:17:24
	System	12 Aug 2020 18:17:24

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-12T14:17:21', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'd326a08d-10ea-4a57-80e7-2958789f5647'	System	12 Aug 2020 18:17:24
User entered 'No (N)'	System	12 Aug 2020 18:17:24

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-12T14:17:23', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'd326a08d-10ea-4a57-80e7-2958789f5647' User entered '12 Aug 2020 14:17'	System	12 Aug 2020 18:17:24
	System	12 Aug 2020 18:17:24

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 3'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-13T12:01:49', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '6930b9f7-0070-4730-badb-4cbb93f6cb97' User entered 'None (0)'	System	14 Aug 2020 18:26:45
	System	14 Aug 2020 18:26:45

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-13T12:01:51', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '6930b9f7-0070-4730-badb-4cbb93f6cb97' User entered 'None (0)'	System	14 Aug 2020 18:26:45
	System	14 Aug 2020 18:26:45

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-13T12:01:53', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '6930b9f7-0070-4730-badb-4cbb93f6cb97' User entered 'None (0)'	System	14 Aug 2020 18:26:45
	System	14 Aug 2020 18:26:45

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-13T12:01:55', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '6930b9f7-0070-4730-badb-4cbb93f6cb97' User entered 'None (0)'	System	14 Aug 2020 18:26:45
	System	14 Aug 2020 18:26:45

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-13T12:02:00', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '6930b9f7-0070-4730-badb-4cbb93f6cb97' User entered 'None (0)'	System	14 Aug 2020 18:26:45
	System	14 Aug 2020 18:26:45

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-13T12:02:02', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '6930b9f7-0070-4730-badb-4cbb93f6cb97' User entered 'None (0)'	System	14 Aug 2020 18:26:45
	System	14 Aug 2020 18:26:45

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-13T12:02:07', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '6930b9f7-0070-4730-badb-4cbb93f6cb97'	System	14 Aug 2020 18:26:45
User entered 'No (N)'	System	14 Aug 2020 18:26:45

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-13T12:02:09', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '6930b9f7-0070-4730-badb-4cbb93f6cb97' User entered '13 Aug 2020 12:02'	System	14 Aug 2020 18:26:45
	System	14 Aug 2020 18:26:45

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 4'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-14T14:27:07', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '5f4c5850-e4a5-478c-8d57-5538bcb33467' User entered 'None (0)'	System	14 Aug 2020 18:27:37
	System	14 Aug 2020 18:27:37

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-14T14:27:08', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '5f4c5850-e4a5-478c-8d57-5538bcb33467' User entered 'None (0)'	System	14 Aug 2020 18:27:37
	System	14 Aug 2020 18:27:37

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-14T14:27:15', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '5f4c5850-e4a5-478c-8d57-5538bcb33467' User entered 'None (0)'	System	14 Aug 2020 18:27:37
	System	14 Aug 2020 18:27:37

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-14T14:27:23', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '5f4c5850-e4a5-478c-8d57-5538bcb33467' User entered 'None (0)'	System	14 Aug 2020 18:27:37
	System	14 Aug 2020 18:27:37

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-14T14:27:26', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '5f4c5850-e4a5-478c-8d57-5538bcb33467' User entered 'None (0)'	System	14 Aug 2020 18:27:37
	System	14 Aug 2020 18:27:37

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-14T14:27:27', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '5f4c5850-e4a5-478c-8d57-5538bcb33467' User entered 'None (0)'	System	14 Aug 2020 18:27:37
	System	14 Aug 2020 18:27:37

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-14T14:27:32', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '5f4c5850-e4a5-478c-8d57-5538bcb33467' User entered 'No (N)'	System	14 Aug 2020 18:27:37
	System	14 Aug 2020 18:27:37

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-14T14:27:34', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '5f4c5850-e4a5-478c-8d57-5538bcb33467' User entered '14 Aug 2020 14:27'	System	14 Aug 2020 18:27:37
	System	14 Aug 2020 18:27:37

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 5'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-15T18:40:22', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '84bc6f32-01bb-486d-b19c-ce6cab21cfd6' User entered 'None (0)'	System	15 Aug 2020 22:40:36
	System	15 Aug 2020 22:40:36

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-15T18:40:23', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '84bc6f32-01bb-486d-b19c-ce6cab21cfd6' User entered 'None (0)'	System	15 Aug 2020 22:40:36
	System	15 Aug 2020 22:40:36

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-15T18:40:25', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '84bc6f32-01bb-486d-b19c-ce6cab21cfd6' User entered 'None (0)'	System	15 Aug 2020 22:40:36
	System	15 Aug 2020 22:40:36

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-15T18:40:26', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '84bc6f32-01bb-486d-b19c-ce6cab21cfd6' User entered 'None (0)'	System	15 Aug 2020 22:40:36
	System	15 Aug 2020 22:40:36

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-15T18:40:28', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '84bc6f32-01bb-486d-b19c-ce6cab21cfd6' User entered 'None (0)'	System	15 Aug 2020 22:40:36
	System	15 Aug 2020 22:40:36

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-15T18:40:29', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '84bc6f32-01bb-486d-b19c-ce6cab21cfd6' User entered 'None (0)'	System	15 Aug 2020 22:40:36
	System	15 Aug 2020 22:40:36

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-15T18:40:31', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '84bc6f32-01bb-486d-b19c-ce6cab21cfd6'	System	15 Aug 2020 22:40:36
User entered 'No (N)'	System	15 Aug 2020 22:40:36

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-15T18:40:33', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '84bc6f32-01bb-486d-b19c-ce6cab21cfd6'	System	15 Aug 2020 22:40:36
User entered '15 Aug 2020 18:40'	System	15 Aug 2020 22:40:36

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 6'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-16T16:34:37', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '1ff210bc-7dad-404d-b50c-56a4a5b4a785' User entered 'None (0)'	System	16 Aug 2020 20:34:54
	System	16 Aug 2020 20:34:54

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-16T16:34:39', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '1ff210bc-7dad-404d-b50c-56a4a5b4a785' User entered 'None (0)'	System	16 Aug 2020 20:34:54
	System	16 Aug 2020 20:34:54

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-16T16:34:40', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '1ff210bc-7dad-404d-b50c-56a4a5b4a785' User entered 'None (0)'	System	16 Aug 2020 20:34:54
	System	16 Aug 2020 20:34:54

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-16T16:34:41', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '1ff210bc-7dad-404d-b50c-56a4a5b4a785' User entered 'None (0)'	System	16 Aug 2020 20:34:54
	System	16 Aug 2020 20:34:54

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-16T16:34:43', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '1ff210bc-7dad-404d-b50c-56a4a5b4a785' User entered 'None (0)'	System	16 Aug 2020 20:34:54
	System	16 Aug 2020 20:34:54

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-16T16:34:44', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '1ff210bc-7dad-404d-b50c-56a4a5b4a785' User entered 'None (0)'	System	16 Aug 2020 20:34:54
	System	16 Aug 2020 20:34:54

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-16T16:34:48', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '1ff210bc-7dad-404d-b50c-56a4a5b4a785' User entered 'No (N)'	System	16 Aug 2020 20:34:54
	System	16 Aug 2020 20:34:54

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-16T16:34:50', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '1ff210bc-7dad-404d-b50c-56a4a5b4a785' User entered '16 Aug 2020 16:34'	System	16 Aug 2020 20:34:54
	System	16 Aug 2020 20:34:54

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 7'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-17T20:27:19', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'a5e075a7-4341-4a9f-9019-16c080187a77' User entered 'None (0)'	System	18 Aug 2020 00:27:44
	System	18 Aug 2020 00:27:44

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-17T20:27:21', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'a5e075a7-4341-4a9f-9019-16c080187a77' User entered 'None (0)'	System	18 Aug 2020 00:27:44
	System	18 Aug 2020 00:27:44

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-17T20:27:23', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'a5e075a7-4341-4a9f-9019-16c080187a77' User entered 'None (0)'	System	18 Aug 2020 00:27:44
	System	18 Aug 2020 00:27:44

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-17T20:27:25', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'a5e075a7-4341-4a9f-9019-16c080187a77' User entered 'None (0)'	System	18 Aug 2020 00:27:44
	System	18 Aug 2020 00:27:44

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-17T20:27:27', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'a5e075a7-4341-4a9f-9019-16c080187a77' User entered 'None (0)'	System	18 Aug 2020 00:27:44
	System	18 Aug 2020 00:27:44

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-17T20:27:28', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'a5e075a7-4341-4a9f-9019-16c080187a77' User entered 'None (0)'	System	18 Aug 2020 00:27:44
	System	18 Aug 2020 00:27:44

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-17T20:27:33', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'a5e075a7-4341-4a9f-9019-16c080187a77'	System	18 Aug 2020 00:27:44
User entered 'No (N)'	System	18 Aug 2020 00:27:44

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-08-17T20:27:42', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'a5e075a7-4341-4a9f-9019-16c080187a77' User entered '17 Aug 2020 20:27'	System	18 Aug 2020 00:27:44
	System	18 Aug 2020 00:27:44

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 18:29:29

US3172040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 18:29:29

US3172040

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 12:28:30

US3172040

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:05:30
	(b) (4)	
User entered '20 Aug 2020'	Mariete Rendon (b) (4)	21 Aug 2020 12:28:30
	(b) (4)	

US3172040

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Contact Made (CONTACT MADE)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 12:28:30

US3172040

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 12:28:30

US3172040

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 12:28:37

US3172040

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'I'	System	21 Aug 2020 12:28:37

US3172040

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 14:55:47

US3172040

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:05:30
	(b) (4)	
User entered '28 Aug 2020'	Jessie Downs (b) (4)	31 Aug 2020 14:55:47
	(b) (4)	

US3172040

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 14:55:47

US3172040

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 14:55:47

US3172040

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 14:55:13

US3172040

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'I'	System	31 Aug 2020 14:55:13

US3172040

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	04 Sep 2020 16:48:47

US3172040

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:05:30
	(b) (4)	
User entered '03 Sep 2020'	Jessie Downs (b) (4)	04 Sep 2020 16:48:47
	(b) (4)	

US3172040

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	04 Sep 2020 16:48:47

US3172040

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	04 Sep 2020 16:48:47

US3172040

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	04 Sep 2020 16:48:50

US3172040

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'I'	System	04 Sep 2020 16:48:50

US3172040

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:36:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:02:45

US3172040

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '8 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:02:45

US3172040

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:02:45

US3172040

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:36:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'VISIT2'	System	08 Sep 2020 16:02:45

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User accepted default value 'Pre-Dose (PREDOSE)'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '8 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:05:30
	(b) (4)	
User entered '09:40'	Mariete Rendon (b) (4)	08 Sep 2020 16:03:55
	(b) (4)	

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered '8 Sep 2020 09:40'	System	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '36.9' C	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '83'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'bpm'	System	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '15'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'breaths/min'	System	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '137'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'mmHg'	System	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '80'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'mmHg'	System	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User accepted default value 'Post-Dose (POSTDOSE)'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 14:17:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 14:17:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 14:17:19
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 16:03:55
User entered empty.	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '8 Sep 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 14:17:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '12:03' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 14:17:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered '8 Sep 2020 12:03'	System	10 Sep 2020 14:17:19
User entered empty.	System	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '37.2' C reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 14:17:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Oral (Oral)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 14:17:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '75' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 14:17:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'bpm'	System	10 Sep 2020 14:17:19
User entered empty.	System	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '16' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 14:17:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'breaths/min'	System	10 Sep 2020 14:17:19
User entered empty.	System	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '140' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 14:17:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'mmHg'	System	10 Sep 2020 14:17:19
User entered empty.	System	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '79' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 14:17:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'mmHg'	System	10 Sep 2020 14:17:19
User entered empty.	System	08 Sep 2020 16:03:55

US3172040

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:36:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:04:03

US3172040

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:36:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '8 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:04:03

US3172040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 15:37:51

US3172040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 15:37:51

US3172040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:21

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)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 15:37:51

US3172040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 15:37:51

US3172040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '8 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 15:37:51

US3172040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '11:33'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 15:37:51

US3172040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered '8 Sep 2020 11:33'	System	08 Sep 2020 15:37:51

US3172040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Left Arm (LEFT ARM)'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 15:37:51

US3172040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'ONCE'	System	08 Sep 2020 15:37:51

US3172040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:21

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 15:37:51

US3172040

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:04:26

US3172040

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '8 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:04:26

US3172040

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '11:02'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:04:26

US3172040

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered '8 Sep 2020 11:02'	System	08 Sep 2020 16:04:26

US3172040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '8 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:04:37

US3172040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:36:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:04:37

US3172040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:36:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:04:37

US3172040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:36:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '11:01'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:04:37

US3172040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered '8 Sep 2020 11:01'	System	08 Sep 2020 16:04:37

US3172040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:36:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:04:37

US3172040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:36:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:04:37

US3172040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:36:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:04:37

US3172040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered empty.	System	08 Sep 2020 16:04:37

US3172040

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 16:04:46

US3172040

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered '1'	System	08 Sep 2020 16:04:46

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	08 Sep 2020 15:37:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T13:45:33', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'b25543f2-903d-461a-85d4-638ccdc24865' User entered 'Yes (Y)'	System	08 Sep 2020 17:46:14
	System	08 Sep 2020 17:46:14

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T13:45:53', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'b25543f2-903d-461a-85d4-638ccdc24865' User entered '98.1'	System	08 Sep 2020 17:46:14
	System	08 Sep 2020 17:46:14

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T13:46:02', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'b25543f2-903d-461a-85d4-638ccdc24865'	System	08 Sep 2020 17:46:14
User entered 'No (N)'	System	08 Sep 2020 17:46:14

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T13:46:12', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: 'b25543f2-903d-461a-85d4-638ccdc24865' User entered '08 Sep 2020 13:46'	System	08 Sep 2020 17:46:14
	System	08 Sep 2020 17:46:14

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '08 Sep 2020 11:53'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '08 Sep 2020 14:23'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	08 Sep 2020 15:37:51
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T19:22:42', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '79c5edd3-74a0-4d42-b17c-5396a6feca34' User entered 'Yes (Y)'	System	08 Sep 2020 23:23:02
	System	08 Sep 2020 23:23:02

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T19:22:12', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '79c5edd3-74a0-4d42-b17c-5396a6feca34' User entered '97.1'	System	08 Sep 2020 23:23:02
	System	08 Sep 2020 23:23:02

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T19:22:23', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '79c5edd3-74a0-4d42-b17c-5396a6feca34' User entered 'No (N)'	System	08 Sep 2020 23:23:02
	System	08 Sep 2020 23:23:02

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T19:22:59', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '79c5edd3-74a0-4d42-b17c-5396a6fee34'	System	08 Sep 2020 23:23:02
User entered '08 Sep 2020 19:22'	System	08 Sep 2020 23:23:02

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '08 Sep 2020 15:18'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	08 Sep 2020 15:37:51
User entered 'Day 2'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	08 Sep 2020 15:37:51
User entered 'Day 3'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	08 Sep 2020 15:37:51
User entered 'Day 4'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	08 Sep 2020 15:37:51
User entered 'Day 5'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	08 Sep 2020 15:37:51
User entered 'Day 6'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	08 Sep 2020 15:37:51
User entered 'Day 7'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	08 Sep 2020 15:37:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '08 Sep 2020 11:53'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '08 Sep 2020 14:23'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	08 Sep 2020 15:37:51
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T19:23:37', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '1a008731-ef15-4898-ac81-9e104e000dca' User entered 'None (1)'	System	08 Sep 2020 23:24:19
	System	08 Sep 2020 23:24:19

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T19:23:44', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '1a008731-ef15-4898-ac81-9e104e000dca' User entered 'No (N)'	System	08 Sep 2020 23:24:19
	System	08 Sep 2020 23:24:19

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T19:23:50', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '1a008731-ef15-4898-ac81-9e104e000dca' User entered 'No (N)'	System	08 Sep 2020 23:24:19
	System	08 Sep 2020 23:24:19

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T19:23:59', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '1a008731-ef15-4898-ac81-9e104e000dca' User entered 'None (1)'	System	08 Sep 2020 23:24:19
	System	08 Sep 2020 23:24:19

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T19:24:16', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '1a008731-ef15-4898-ac81-9e104e000dca' User entered '08 Sep 2020 19:24'	System	08 Sep 2020 23:24:19
	System	08 Sep 2020 23:24:19

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '08 Sep 2020 15:18'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	08 Sep 2020 15:37:51
User entered 'Day 2'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	08 Sep 2020 15:37:51
User entered 'Day 3'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	08 Sep 2020 15:37:51
User entered 'Day 4'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	08 Sep 2020 15:37:51
User entered 'Day 5'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	08 Sep 2020 15:37:51
User entered 'Day 6'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	08 Sep 2020 15:37:51
User entered 'Day 7'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	08 Sep 2020 15:37:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T13:42:58', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '70e450e7-5389-455d-9bde-61c98048961e' User entered 'None (0)'	System	08 Sep 2020 17:44:56
	System	08 Sep 2020 17:44:56

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T13:43:16', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '70e450e7-5389-455d-9bde-61c98048961e'	System	08 Sep 2020 17:44:56
User entered 'No interference with activity (1)'	System	08 Sep 2020 17:44:56

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T13:43:30', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '70e450e7-5389-455d-9bde-61c98048961e' User entered 'No interference with activity (1)'	System	08 Sep 2020 17:44:56
	System	08 Sep 2020 17:44:56

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T13:43:44', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '70e450e7-5389-455d-9bde-61c98048961e' User entered 'No interference with activity (1)'	System	08 Sep 2020 17:44:56
	System	08 Sep 2020 17:44:56

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T13:43:58', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '70e450e7-5389-455d-9bde-61c98048961e'	System	08 Sep 2020 17:44:56
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	08 Sep 2020 17:44:56

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T13:44:05', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '70e450e7-5389-455d-9bde-61c98048961e'	System	08 Sep 2020 17:44:56
User entered 'No interference with activity (1)'	System	08 Sep 2020 17:44:56

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T13:44:15', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '70e450e7-5389-455d-9bde-61c98048961e' User entered 'No (N)'	System	08 Sep 2020 17:44:56
	System	08 Sep 2020 17:44:56

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T13:44:53', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '70e450e7-5389-455d-9bde-61c98048961e' User entered '08 Sep 2020 13:44'	System	08 Sep 2020 17:44:56
	System	08 Sep 2020 17:44:56

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '08 Sep 2020 11:53'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '08 Sep 2020 14:23'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	08 Sep 2020 15:37:51
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T19:25:48', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '25d883b7-091a-43f2-8498-aaf923ab3fd6'	System	08 Sep 2020 23:27:50
User entered 'No interference with activity (1)'	System	08 Sep 2020 23:27:50

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T19:26:08', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '25d883b7-091a-43f2-8498-aaf923ab3fd6'	System	08 Sep 2020 23:27:50
User entered 'No interference with activity (1)'	System	08 Sep 2020 23:27:50

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T19:26:33', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '25d883b7-091a-43f2-8498-aaf923ab3fd6'	System	08 Sep 2020 23:27:50
User entered 'No interference with activity (1)'	System	08 Sep 2020 23:27:50

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T19:26:49', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '25d883b7-091a-43f2-8498-aaf923ab3fd6'	System	08 Sep 2020 23:27:50
User entered 'No interference with activity (1)'	System	08 Sep 2020 23:27:50

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T19:27:06', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '25d883b7-091a-43f2-8498-aaf923ab3fd6'	System	08 Sep 2020 23:27:50
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	08 Sep 2020 23:27:50

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T19:27:19', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '25d883b7-091a-43f2-8498-aaf923ab3fd6'	System	08 Sep 2020 23:27:50
User entered 'No interference with activity (1)'	System	08 Sep 2020 23:27:50

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T19:27:30', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '25d883b7-091a-43f2-8498-aaf923ab3fd6' User entered 'No (N)'	System	08 Sep 2020 23:27:50
	System	08 Sep 2020 23:27:50

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAB8A0E8-849A-4881-9A9F-98EA7CA777B5)', Time: '2020-09-08T19:27:47', User OID: 'PatientReportedOutcome (US3172040)', ODM File OID: '25d883b7-091a-43f2-8498-aaf923ab3fd6' User entered '08 Sep 2020 19:27'	System	08 Sep 2020 23:27:50
	System	08 Sep 2020 23:27:50

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '08 Sep 2020 15:18'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	08 Sep 2020 15:37:51
User entered 'Day 2'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	08 Sep 2020 15:37:51
User entered 'Day 3'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	08 Sep 2020 15:37:51
User entered 'Day 4'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	08 Sep 2020 15:37:51
User entered 'Day 5'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	08 Sep 2020 15:37:51
User entered 'Day 6'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
Data entry locked.	System	08 Sep 2020 15:37:51
User entered 'Day 7'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:21

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 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 15:37:51

US3172040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:57:05
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 15:37:51

US3172040

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Sep 2020 20:48:52

US3172040

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:05:30
	(b) (4)	
User entered '15 Sep 2020'	Jessie Downs (b) (4)	23 Sep 2020 20:48:52
	(b) (4)	

US3172040

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	23 Sep 2020 20:48:52

US3172040

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Sep 2020 20:48:52

US3172040

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Sep 2020 20:49:07

US3172040

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'I'	System	23 Sep 2020 20:49:07

US3172040

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Sep 2020 20:49:25

US3172040

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:05:30
	(b) (4)	
User entered '23 Sep 2020'	Jessie Downs (b) (4)	23 Sep 2020 20:49:25
	(b) (4)	

US3172040

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	23 Sep 2020 20:49:25

US3172040

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Sep 2020 20:49:25

US3172040

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Sep 2020 20:49:31

US3172040

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'I'	System	23 Sep 2020 20:49:31

US3172040

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 18:04:37

US3172040

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:05:30
	(b) (4)	
User entered '29 Sep 2020'	Jessie Downs (b) (4)	30 Sep 2020 18:04:37
	(b) (4)	

US3172040

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:05:30
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4)	30 Sep 2020 18:04:37
	(b) (4)	

US3172040

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 18:04:37

US3172040

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 18:04:42

US3172040

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'I'	System	30 Sep 2020 18:04:42

US3172040

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:36:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 14:48:59

US3172040

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '6 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 14:48:59

US3172040

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 14:48:59

US3172040

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:36:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'VISIT3'	System	06 Oct 2020 14:48:59

US3172040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 14:49:19

US3172040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '6 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 14:49:19

US3172040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:05:30
	(b) (4)	
User entered '09:00'	Mariete Rendon (b) (4)	06 Oct 2020 14:49:19
	(b) (4)	

US3172040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered '6 Oct 2020 09:00'	System	06 Oct 2020 14:49:19

US3172040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '37.0' C	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 14:49:19

US3172040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 14:49:19

US3172040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 14:49:19

US3172040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '87'	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 14:49:19

US3172040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'bpm'	System	06 Oct 2020 14:49:19

US3172040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '16'	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 14:49:19

US3172040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'breaths/min'	System	06 Oct 2020 14:49:19

US3172040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '136'	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 14:49:19

US3172040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'mmHg'	System	06 Oct 2020 14:49:19

US3172040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '80'	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 14:49:19

US3172040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered 'mmHg'	System	06 Oct 2020 14:49:19

US3172040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43

US3172040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43

US3172040

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:36:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 14:49:22

US3172040

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:36:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 14:49:22

US3172040

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 14:49:36

US3172040

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '6 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 14:49:36

US3172040

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '09:38'	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 14:49:36

US3172040

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered '6 Oct 2020 09:38'	System	06 Oct 2020 14:49:36

US3172040

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 14:49:40

US3172040

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered '1'	System	06 Oct 2020 14:49:40

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 64'	System	11 Aug 2020 18:29:29

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26
Data entry locked.	System	11 Aug 2020 18:29:29
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 18:29:29

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26
Data entry locked.	System	11 Aug 2020 18:29:29
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 18:29:29

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 71'	System	11 Aug 2020 18:29:29

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3172040

Folder: Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26
Data entry locked.	System	11 Aug 2020 18:29:29
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 18:29:29

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26
Data entry locked.	System	11 Aug 2020 18:29:29
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 18:29:29

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 78'	System	11 Aug 2020 18:29:29

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:36:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

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Folder: Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26
Data entry locked.	System	11 Aug 2020 18:29:29
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 18:29:29

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26
Data entry locked.	System	11 Aug 2020 18:29:29
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 18:29:29

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 92'	System	11 Aug 2020 18:29:29

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26
Data entry locked.	System	11 Aug 2020 18:29:29
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 18:29:29

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26
Data entry locked.	System	11 Aug 2020 18:29:29
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 18:29:29

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26
Data entry locked.	System	11 Aug 2020 18:29:29
User entered 'Day 99'	System	11 Aug 2020 18:29:29

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26
Data entry locked.	System	11 Aug 2020 18:29:29
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 18:29:29

US3172040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:24:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:26
Data entry locked.	System	11 Aug 2020 18:29:29
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 18:29:29

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 03:48:26

US3172040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:26
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 03:48:26

US3172040

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	03 Nov 2020 13:58:52

US3172040

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '2 Nov 2020'	Mariete Rendon (b) (4) (b) (4)	03 Nov 2020 13:58:52

US3172040

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Contact Made (CONTACT MADE)'	Mariete Rendon (b) (4) (b) (4)	03 Nov 2020 13:58:52

US3172040

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Nov 2020 13:58:52

US3172040

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	07 Dec 2020 20:57:55
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	03 Nov 2020 13:59:01

US3172040

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:43
User entered '1'	System	07 Dec 2020 20:57:55
User entered empty.	System	03 Nov 2020 13:59:01

US3172040

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:59:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	07 Dec 2020 20:58:09

US3172040

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:59:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '07 Dec 2020'	Jessie Downs (b) (4) (b) (4)	07 Dec 2020 20:58:09

US3172040

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:59:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	07 Dec 2020 20:58:09

US3172040

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:59:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	07 Dec 2020 20:58:09

US3172040

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:59:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	07 Dec 2020 20:58:19

US3172040

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:59:27
User entered 'I'	System	07 Dec 2020 20:58:19

US3172040

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:59:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	07 Jan 2021 21:34:07

US3172040

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:59:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:05:30
	(b) (4)	
User entered '07 Jan 2021'	Jessie Downs (b) (4)	07 Jan 2021 21:34:07
	(b) (4)	

US3172040

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:59:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	07 Jan 2021 21:34:07

US3172040

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:59:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	07 Jan 2021 21:34:07

US3172040

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:59:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	07 Jan 2021 21:33:46

US3172040

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:59:27
User entered 'I'	System	07 Jan 2021 21:33:46

US3172040

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:59:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 16:56:22

US3172040

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:59:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '05 Feb 2021'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 16:56:22

US3172040

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:59:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:05:30
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4)	08 Feb 2021 16:56:22
	(b) (4)	

US3172040

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:59:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 16:56:22

US3172040

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:59:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 16:56:08

US3172040

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 12:59:27
User entered 'I'	System	08 Feb 2021 16:56:08

US3172040

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:36:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:04:02

US3172040

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered '12 Mar 2021'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:04:02

US3172040

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:36:21

[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 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:04:02

US3172040

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:36:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered 'VISIT4'	System	12 Mar 2021 20:04:02

US3172040

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 17:54:19

US3172040

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered '12 Mar 2021'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 17:54:19

US3172040

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered '07:40'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 17:54:19

US3172040

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered '12 Mar 2021 07:40'	System	30 Mar 2021 17:54:19

US3172040

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered '36.9' C	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 17:54:19

US3172040

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 17:54:19

US3172040

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 17:54:19

US3172040

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered '76'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 17:54:19

US3172040

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered 'bpm'	System	30 Mar 2021 17:54:19

US3172040

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered '17'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 17:54:19

US3172040

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered 'breaths/min'	System	30 Mar 2021 17:54:19

US3172040

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered '157'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 17:54:19

US3172040

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered 'mmHg'	System	30 Mar 2021 17:54:19

US3172040

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered '90'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 17:54:19

US3172040

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered 'mmHg'	System	30 Mar 2021 17:54:19

US3172040

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55

US3172040

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:21

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55

US3172040

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:36:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:04:37

US3172040

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:36:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered '12 Mar 2021'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:04:37

US3172040

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:04:24

US3172040

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered '12 Mar 2021'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:04:24

US3172040

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered '08:56'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:04:24

US3172040

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered '12 Mar 2021 08:56'	System	12 Mar 2021 20:04:24

US3172040

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:04:44

US3172040

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:55
User entered 'I'	System	12 Mar 2021 20:04:44

US3172040

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	06 Apr 2021 20:31:52

US3172040

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered '06 Apr 2021'	(b) (4), (b) (6)	06 Apr 2021 20:31:52

US3172040

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 20:31:52

US3172040

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 20:31:52

US3172040

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	06 Apr 2021 20:32:02

US3172040

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Apr 2021 20:32:02

US3172040

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

Form: Visit Date

Generated On: 09 Jun 2021 15:36:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Jan 2021 19:29:04

US3172040

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

Form: Visit Date

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '25 Jan 2021'	Jessie Downs (b) (4) (b) (4)	25 Jan 2021 19:29:04

US3172040

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

Form: Visit Date

Generated On: 09 Jun 2021 15:36:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	25 Jan 2021 19:29:04

US3172040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:36:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:38
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 19:29:04

US3172040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:36:21

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '06 Jan 2021'	Jessie Downs (b) (4) (b) (4)	25 Jan 2021 19:28:52

US3172040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:36:21

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 20:57:34
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:33:51

US3172040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:36:21

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Jan 2021 19:28:52

US3172040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:36:21

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 12:23:18
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'Data updated ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 20:57:56
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	09 Apr 2021 20:57:34
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 20:33:20
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:33:51

US3172040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:36:21

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '25 Jan 2021'	Jessie Downs (b) (4) (b) (4)	25 Jan 2021 19:28:52

US3172040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:36:21

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'mRNA-1273 (mRNA-1273)'	Jessie Downs (b) (4) (b) (4)	25 Jan 2021 19:28:52

US3172040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:36:21

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'mRNA-1273 (mRNA-1273)'	Jessie Downs (b) (4) (b) (4)	25 Jan 2021 19:28:52

US3172040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:36:21

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'mRNA-1273 (mRNA-1273)'	Jessie Downs (b) (4) (b) (4)	25 Jan 2021 19:28:52

US3172040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:36:21

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	25 Jan 2021 19:28:52

US3172040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:36:21

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:38
User entered empty.	System	25 Jan 2021 19:28:52

US3172040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:36:21

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:38
User entered empty.	System	25 Jan 2021 19:28:52

US3172040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Jan 2021 19:28:23

US3172040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '25 Jan 2021'	Jessie Downs (b) (4) (b) (4)	25 Jan 2021 19:28:23

US3172040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '11:00'	Jessie Downs (b) (4) (b) (4)	25 Jan 2021 19:28:23

US3172040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:38
User entered '25 Jan 2021 11:00'	System	25 Jan 2021 19:28:23

US3172040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:36:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Jan 2021 19:28:04

US3172040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:36:21

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '25 Jan 2021'	Jessie Downs (b) (4) (b) (4)	25 Jan 2021 19:28:04

US3172040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:36:21

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:38
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:05:30
	(b) (4)	
User entered '11:01' reason for change: Data Entry Error	Jessie Downs (b) (4)	25 Jan 2021 19:28:09
	(b) (4)	
User entered '11:00'	Jessie Downs (b) (4)	25 Jan 2021 19:28:04
	(b) (4)	

US3172040

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:36:21

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:55:38
User entered '25 Jan 2021 11:01'	System	25 Jan 2021 19:28:09
User entered '25 Jan 2021 11:00'	System	25 Jan 2021 19:28:04

US3172040

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:36:21

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:54:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:24:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:24:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	28 Aug 2020 13:53:58

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:41:45
User entered 'USA-US118-2021-mRNA-1273-P301000010'	System	15 Mar 2021 14:41:39
User entered 'New'	(b) (4), (b) (6)	15 Mar 2021 14:41:39

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Mar 2021 22:10:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Mar 2021 22:10:49
Data point term sent to Coder	System	12 Mar 2021 20:29:19
User entered 'acute exacerbation of gout'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered '21 Feb 2021'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered '22 Feb 2021'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Mar 2021 17:56:15
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessie Downs (b) (4)	12 Mar 2021 20:29:09
	(b) (4)	

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Mar 2021 17:56:15
	(b) (4)	
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	12 Mar 2021 20:29:28
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	12 Mar 2021 20:29:09
User entered 'Yes (Y)'	Jessie Downs (b) (4)	12 Mar 2021 20:29:09
	(b) (4)	

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered '0'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered '0'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Mar 2021 17:56:15
	(b) (4)	
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		12 Mar 2021 20:29:28
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		12 Mar 2021 20:29:28
User entered '1' reason for change: Data Entry Error	Jessie Downs (b) (4)	12 Mar 2021 20:29:28
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	12 Mar 2021 20:29:09
User entered '0'	Jessie Downs (b) (4)	12 Mar 2021 20:29:09
	(b) (4)	

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered '21 Feb 2021'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered '22 Feb 2021'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered '0'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered '0'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered '0'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered 'Not Applicable (NOT APPLICABLE)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

None

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 07:07:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered 'I'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered '0'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered '0'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 18:38:04
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)	22 Mar 2021 18:37:49
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)	22 Mar 2021 18:37:38
User signature succeeded.	Mark Kutner (b) (4)	16 Mar 2021 17:56:15
	(b) (4)	
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	12 Mar 2021 20:33:47
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	12 Mar 2021 20:33:47

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CAME TODAY FOR VISIT 209 AS PER PROTOCOL. HE REPORTED BEEN ADMITTED TO MERCY HOSPITAL ON 21FEB2020 AT 7:00 PM DUE TO ACUTE EXACERBATION OF GOUT, MANIFESTED WITH SEVERE JOINT PAIN IN THE RIGHT HAND POINTED FINGER (TUBERELE OF TRAPEZIUM AND RIGHT BIG TOE). TODAY SUBJECT IS ASYMPTOMATIC AND DENIES ANY SYMPTOMS OR PAIN AT TIME OF VISIT. WE WILL REQUEST MEDICAL RECORDS AND UPDATE SAE WHEN DOCUMENTS ARE RECEIVED.' reason for change: Data Entry Error	Jessie Downs (b) (4)	12 Mar 2021 20:33:47
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	12 Mar 2021 20:29:09
User entered empty.	Jessie Downs (b) (4)	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Mar 2021 20:29:09

US3172040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Mar 2021 20:29:09

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:36:21

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:54:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	15 Sep 2020 21:01:53
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	02 Sep 2020 14:38:20

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:05:30
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 21:03:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 21:03:48
	(b) (4)	
Data point term sent to Coder	System	15 Sep 2020 21:03:13
User entered 'lisinopril'	Mariete Rendon (b) (4)	15 Sep 2020 21:02:24
	(b) (4)	

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	15 Sep 2020 21:02:24

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'hypertension'	Mariete Rendon (b) (4) (b) (4)	15 Sep 2020 21:02:24

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '20'	Mariete Rendon (b) (4) (b) (4)	15 Sep 2020 21:02:24

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	15 Sep 2020 21:02:24

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	15 Sep 2020 21:02:24

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'once daily (QD)'	Mariete Rendon (b) (4) (b) (4)	15 Sep 2020 21:02:24

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	15 Sep 2020 21:02:24

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	15 Sep 2020 21:02:24

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	15 Sep 2020 21:02:24

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'un UNK 2005'	Mariete Rendon (b) (4) (b) (4)	15 Sep 2020 21:02:24

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	15 Sep 2020 21:02:24

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	15 Sep 2020 21:02:24

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	15 Sep 2020 21:02:24

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	15 Sep 2020 21:02:24

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 21:02:24

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 21:02:24

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 21:02:24

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:13:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:13:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
Data point term sent to Coder	System	12 Mar 2021 20:06:57
User entered 'esatalopram'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:06:15

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:06:15

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered 'anxiety'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:06:15

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered '20'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:06:15

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:06:15

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:06:15

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:06:15

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:06:15

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:06:15

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:06:15

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered 'un UNK 2003'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:06:15

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered '0'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:06:15

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:06:15

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:06:15

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:06:15

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Mar 2021 20:06:15

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Mar 2021 20:06:15

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Mar 2021 20:06:15

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM, PRODUCT: COLCHICINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 20:08:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 20:08:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
Data point term sent to Coder	System	12 Mar 2021 20:07:57
User entered 'colchicine'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:07:20

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:07:20

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered 'gout'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:07:20

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered '0.6'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:07:20

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:07:20

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:07:20

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered 'twice daily (BID)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:07:20

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:07:20

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:07:20

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:07:20

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered 'un UNK 2010'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:07:20

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered '0'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:07:20

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:07:20

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:07:20

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:08:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:07:20

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Mar 2021 20:07:20

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Mar 2021 20:07:20

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Mar 2021 20:07:20

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:21

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:00:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:00:49
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
Data point term sent to Coder	System	12 Mar 2021 20:25:14
User entered 'ibuprofen'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:24:32

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:24:32

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered 'pain from gout excess'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:24:32

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered '800'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:24:32

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:24:32

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:24:32

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered 'as needed (PRN)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:24:32

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:24:32

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:24:32

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:24:32

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered 'un UNK 2010'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:24:32

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered '0'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:24:32

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:24:32

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:24:32

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	12 Mar 2021 20:24:32

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 20:24:32

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 20:24:32

US3172040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 20:24:32

US3172040

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:36:21

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:05:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	28 Aug 2020 13:54:09

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Mar 2021 17:56:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:42:26
User entered 'USA-US118-2021-MRNA-1273-P301000010'	System	15 Mar 2021 14:41:39

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Mar 2021 17:56:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:42:26
User entered 'Yes (Y)'	System	15 Mar 2021 14:41:39

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Mar 2021 17:56:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:42:26
User entered 'No (N)'	System	15 Mar 2021 14:41:39

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:42:26
User entered 'No (N)'	System	15 Mar 2021 14:41:39

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:42:26
User entered 'Yes (Y)'	System	15 Mar 2021 14:41:39

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:42:26
User entered 'No (N)'	System	15 Mar 2021 14:41:39

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:42:26
User entered 'No (N)'	System	15 Mar 2021 14:41:39

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:42:26
User entered 'No (N)'	System	15 Mar 2021 14:41:39

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:42:26
User entered 'Mark'	System	15 Mar 2021 14:41:39

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:42:26
User entered 'Kutner'	System	15 Mar 2021 14:41:39

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:42:26
User entered 'FL'	System	15 Mar 2021 14:41:39

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Mar 2021 17:56:15
	(b) (4)	
User entered 'US'	System	15 Mar 2021 14:42:34

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Mar 2021 14:42:34

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Mar 2021 17:56:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:42:26
User entered		
'USA-US118-2021-MRNA-1273-P301000010'	System	15 Mar 2021 14:41:39

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Mar 2021 17:56:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:42:26
User entered 'Yes (Y)'	System	15 Mar 2021 14:41:39

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Mar 2021 17:56:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:42:26
User entered 'No (N)'	System	15 Mar 2021 14:41:39

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:42:26
User entered 'No (N)'	System	15 Mar 2021 14:41:39

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Mar 2021 17:56:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:42:26
User entered 'Yes (Y)'	System	15 Mar 2021 14:41:39

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:42:26
User entered 'No (N)'	System	15 Mar 2021 14:41:39

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:42:26
User entered 'No (N)'	System	15 Mar 2021 14:41:39

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:42:26
User entered 'No (N)'	System	15 Mar 2021 14:41:39

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:42:26
User entered 'Mark'	System	15 Mar 2021 14:41:39

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:42:26
User entered 'Kutner'	System	15 Mar 2021 14:41:39

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:42:26
User entered 'FL'	System	15 Mar 2021 14:41:39

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Mar 2021 17:56:15
	(b) (4)	
User entered 'US'	System	15 Mar 2021 14:42:34

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Mar 2021 14:42:34

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:36:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Mar 2021 17:56:15
	(b) (4)	
User entered '15/Mar/2021 10:42'	System	15 Mar 2021 14:42:34

US3172040

Folder: SAE USA-US118-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:36:21

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.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:56:15
User entered 'I'	(b) (4), (b) (6)	15 Mar 2021 14:42:34