

US3702040 (Prod: Weill Cornell Chelsea - (CRS))

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3702040

Form: Participant Creation

Data signed: (b) (4) 16 Apr 2021 13:26:04

Generated On: 10 Jun 2021 09:18:52

Participant ID

US3702040

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

US3702040

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Date of Birth (MMM yyyy)	(b) (6) 1961
Age	58
Age Units	YEARS
Age (Derived)	59
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 19:21:34

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Date of Informed Consent (*dd MMM yyyy*) 21 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input checked="" type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify _____

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number _____

Enrollment Trigger 1

US3702040

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 16 Apr 2021 13:28:48

Generated On: 10 Jun 2021 09:18:52

Condition	GUN SHOT WOUND OF CHEST CAVITY
Start date (dd MMM yyyy)	UN UNK 1967
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 1967
Start Year (derived)	1967
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 16 Apr 2021 13:28:48

Generated On: 10 Jun 2021 09:18:52

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3702040

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 16 Apr 2021 13:28:48

Generated On: 10 Jun 2021 09:18:52

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3702040

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 16 Apr 2021 13:28:48

Generated On: 10 Jun 2021 09:18:52

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 16 Apr 2021 13:28:48

Generated On: 10 Jun 2021 09:18:52

Condition	FACIAL PAIN
Start date (dd MMM yyyy)	31 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)	_____

US3702040

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 16 Apr 2021 13:28:48

Generated On: 10 Jun 2021 09:18:52

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:30 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 09:30
Height (<i>xxx.x</i>)	168 cm
Weight (<i>xxx.x</i>)	85.4 kg
BMI (<i>xxx.x</i>)	30.25794 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 19:21:34

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☐

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 19:21:34

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

What was the date of randomization? (dd MMM yyyy) 21 SEP 2020

What was the participant's randomization number? 145184

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☐
 >=18 and <65 years and at risk ☒
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

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)	21 SEP 2020
Time of assessment (00:00-23:59)	09:30 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 09:30
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

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)	21 SEP 2020
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 12:00
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

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) 21 SEP 2020

What was the treatment time? (00:00-23:59) 11:29 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 11:29

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 21 SEP 2020

Collection time (00:00-23:59) 10:15 (24 HR)

Collection date and time (derived) 21 SEP 2020 10:15

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:25	21 SEP 2020 10:25
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 12:00

PC Open Date & Time

21 SEP 2020 11:49

PC Close Date & Time

21 SEP 2020 14:19

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

PC Time Stamp	21 SEP 2020 17:43
PC Open Date & Time	21 SEP 2020 15:14
PC Close Date & Time	22 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:52

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 19:28

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:52

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

99.1 °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

23 SEP 2020 16:53

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:52

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

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 18:19

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:52

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

99.1 °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

26 SEP 2020 00:30

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:52

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 16:38

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

28 SEP 2020 05:47

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

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

21 SEP 2020 12:01

PC Open Date & Time

21 SEP 2020 11:49

PC Close Date & Time

21 SEP 2020 14:19

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

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

21 SEP 2020 17:44

PC Open Date & Time

21 SEP 2020 15:14

PC Close Date & Time

22 SEP 2020 11:59

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:52

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

22 SEP 2020 19:29

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:52

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

23 SEP 2020 16:53

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:52

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

24 SEP 2020 18:19

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:52

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

26 SEP 2020 00:30

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:52

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

26 SEP 2020 16:38

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:52

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

28 SEP 2020 05:47

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 12:01
PC Open Date & Time	21 SEP 2020 11:49
PC Close Date & Time	21 SEP 2020 14:19

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 17:44
PC Open Date & Time	21 SEP 2020 15:14
PC Close Date & Time	22 SEP 2020 11:59

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:52

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 ☒

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:52

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 19:29
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:52

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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US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:52

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 16:54
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:52

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 18:20
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:52

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 ☒

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:52

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 00:30
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:52

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 ☒

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:52

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 16:38
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:52

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 ☒

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:52

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 05:48
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3702040

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 28 SEP 2020 20:20

PC Open Date & Time 28 SEP 2020 12:00

PC Close Date & Time 29 SEP 2020 11:59

US3702040

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 30 SEP 2020 07:33

PC Open Date & Time 29 SEP 2020 12:00

PC Close Date & Time 30 SEP 2020 11:59

US3702040

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	28 SEP 2020 20:20
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3702040

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 SEP 2020 07:33
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3702040

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3702040

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702040

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3702040

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702040

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3702040

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702040

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

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

Visit date (dd MMM yyyy)	20 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 OCT 2020
Time of assessment (00:00-23:59)	09:35 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 09:35
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)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

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)	20 OCT 2020
Time of assessment (00:00-23:59)	10:39 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 10:39
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3702040

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 OCT 2020

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

US3702040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

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) 20 OCT 2020

What was the treatment time? (00:00-23:59) 10:05 (24 HR)

Treatment Date and Time (derived) 20 OCT 2020 10:05

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

US3702040

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 OCT 2020

Collection time (00:00-23:59)

09:55 (24 HR)

Collection date and time (derived)

20 OCT 2020 09:55

US3702040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Collection date (dd MMM yyyy)			20 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:02	20 OCT 2020 10:02
Nasopharyngeal Swab 2	No		

US3702040

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

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

20 OCT 2020 10:40

PC Open Date & Time

20 OCT 2020 10:25

PC Close Date & Time

20 OCT 2020 12:55

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	20 OCT 2020 20:34
PC Open Date & Time	20 OCT 2020 13:50
PC Close Date & Time	21 OCT 2020 11:59

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

21 OCT 2020 18:18

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 OCT 2020 17:30

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:52

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 OCT 2020 20:33

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

24 OCT 2020 15:58

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 OCT 2020 00:34

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:52

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 OCT 2020 19:01

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

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

20 OCT 2020 10:41

PC Open Date & Time

20 OCT 2020 10:25

PC Close Date & Time

20 OCT 2020 12:55

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

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

20 OCT 2020 20:35

PC Open Date & Time

20 OCT 2020 13:50

PC Close Date & Time

21 OCT 2020 11:59

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:52

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

21 OCT 2020 18:18

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:52

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

22 OCT 2020 17:30

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:52

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

23 OCT 2020 20:34

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:52

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

24 OCT 2020 15:58

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:52

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

26 OCT 2020 00:34

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:52

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

26 OCT 2020 19:01

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

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

No ☒

Yes ☐

PC Time stamp	20 OCT 2020 10:41
PC Open Date & Time	20 OCT 2020 10:25
PC Close Date & Time	20 OCT 2020 12:55

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

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

No ☒
Yes ☐

PC Time stamp	20 OCT 2020 20:35
PC Open Date & Time	20 OCT 2020 13:50
PC Close Date & Time	21 OCT 2020 11:59

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:52

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
EAB) (1725)

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US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:52

Yes <input type="checkbox"/>	
PC Time stamp	21 OCT 2020 18:31
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:52

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
EAB) (1725)

99 of 2145

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:52

Yes <input type="checkbox"/>	
PC Time stamp	22 OCT 2020 17:31
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:52

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 ☒

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:52

Yes <input type="checkbox"/>	
PC Time stamp	23 OCT 2020 20:34
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:52

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 ☒

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:52

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 15:58
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:52

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 ☒

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:52

Yes <input type="checkbox"/>	
PC Time stamp	26 OCT 2020 00:34
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:52

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 ☒

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:52

Yes <input type="checkbox"/>	
PC Time stamp	26 OCT 2020 19:02
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3702040

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3702040

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702040

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3702040

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702040

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3702040

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702040

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3702040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 NOV 2020
Time of assessment (00:00-23:59)	10:37 (24 HR)
Vital Signs Date and Time (derived)	17 NOV 2020 10:37
Temperature (xxx.x)	35.8 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3702040

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 NOV 2020

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

US3702040

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

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

Collection date (dd MMM yyyy)	17 NOV 2020
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Collection time (00:00-23:59)	09:44 (24 HR)
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Collection date and time (derived)	17 NOV 2020 09:44
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US3702040

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:21:34

Generated On: 10 Jun 2021 09:18:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT	DAY 61
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"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 17:59:28
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 DEC 2020 14:25:02
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 17:59:22
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	20 DEC 2020 11:59:47
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 2020 00:01
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Patient Cloud Close Date & Time	27 DEC 2020 23:59
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US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 11:59:42

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 12:00:57

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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="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"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 18:34:53

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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°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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 FEB 2021 12:00:30

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 FEB 2021 14:40:49

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 13:47:19

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 13:31:19

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

14 MAR 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 12:07:10

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 18:11:28

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 11:59:25

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

07 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 12:00:21

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 19:11:09

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 12:20:44

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 <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"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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°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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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="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"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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°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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

20 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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="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"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 FEB 2022 00:01
Patient Cloud Close Date & Time	27 FEB 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 <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"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 <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"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JUN 2022 00:01
Patient Cloud Close Date & Time	03 JUL 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JUL 2022 00:01
Patient Cloud Close Date & Time	17 JUL 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	14 AUG 2022 23:59
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US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 <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"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

30 OCT 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 <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"/>

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

13 NOV 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

20 NOV 2022 23:59

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

[Patient Cloud Close Date & Time](#)

27 NOV 2022 23:59

US3702040

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:18:52

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
Yes	No	28 FEB 2021 13:47:04

US3702040

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 20:55:17

Generated On: 10 Jun 2021 09:18:52

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3702040

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:55:17

Generated On: 10 Jun 2021 09:18:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702040

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 13:28:47

Generated On: 10 Jun 2021 09:18:52

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3702040

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 13:28:47

Generated On: 10 Jun 2021 09:18:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702040

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 13:28:47

Generated On: 10 Jun 2021 09:18:52

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3702040

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 13:28:47

Generated On: 10 Jun 2021 09:18:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702040

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 13:28:47

Generated On: 10 Jun 2021 09:18:52

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3702040

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 13:28:47

Generated On: 10 Jun 2021 09:18:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702040

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:29:42

Generated On: 10 Jun 2021 09:18:52

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

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

Folder OID	VISIT4
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US3702040

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:52

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.

US3702040

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:29:42

Generated On: 10 Jun 2021 09:18:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702040

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3702040

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:18:52

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

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Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:18:52

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 13:26:05

Generated On: 10 Jun 2021 09:18:52

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

Visit date (dd MMM yyyy)	11 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3702040

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 13:26:05

Generated On: 10 Jun 2021 09:18:52

Date of updated informed consent (<i>dd MMM yyyy</i>)	11 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	11 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Apr 2021 13:28:47

Generated On: 10 Jun 2021 09:18:52

Height	170.1 cm
Weight	84.2 kg
BMI (xxx.x)	29.10070

US3702040

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 13:28:47

Generated On: 10 Jun 2021 09:18:52

Height	170.1 cm
Weight	84.2 kg
BMI (xxx.x)	29.10070
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 JAN 2021
Time of assessment (00:00-23:59)	10:07 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 10:07
Temperature (xxx.x)	96.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3702040

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 13:28:47

Generated On: 10 Jun 2021 09:18:52

Height	170.1 cm
Weight	84.2 kg
BMI (xxx.x)	29.10070
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 JAN 2021
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 13:26:05

Generated On: 10 Jun 2021 09:18:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 JAN 2021

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

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

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 13:26:05

Generated On: 10 Jun 2021 09:18:52

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 11 JAN 2021

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

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

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

What was the frequency of the study treatment dosing? ONCE

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

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 13:26:05

Generated On: 10 Jun 2021 09:18:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 JAN 2021

Collection time (00:00-23:59)

10:39 (24 HR)

Collection date and time (derived)

11 JAN 2021 10:39

US3702040

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 13:26:05

Generated On: 10 Jun 2021 09:18:52

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

Collection date (dd MMM yyyy)	11 JAN 2021
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Collection time (00:00 - 23:59)	11:11
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Collection Date and Time (derived)	11 JAN 2021 11:11
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Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 13:26:05

Generated On: 10 Jun 2021 09:18:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702040

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 13:28:48

Generated On: 10 Jun 2021 09:18:52

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3702040

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 13:28:48

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 13:26:05

Generated On: 10 Jun 2021 09:18:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 13:26:05

Generated On: 10 Jun 2021 09:18:52

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 FEB 2021
Time of assessment (00:00-23:59)	09:33 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 09:33
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 13:26:05

Generated On: 10 Jun 2021 09:18:52

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)	08 FEB 2021
Time of assessment (00:00-23:59)	11:03 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 11:03
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFORMATION NOT SPECIFIED
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 13:26:05

Generated On: 10 Jun 2021 09:18:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 FEB 2021

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

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Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 13:26:05

Generated On: 10 Jun 2021 09:18:52

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 08 FEB 2021

What was the treatment time? (00:00-23:59) 10:30 (24 HR)

Treatment Date and Time (derived) 08 FEB 2021 10:30

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: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 13:26:05

Generated On: 10 Jun 2021 09:18:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 13:28:47

Generated On: 10 Jun 2021 09:18:52

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3702040

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 13:28:47

Generated On: 10 Jun 2021 09:18:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702040

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 13:26:05

Generated On: 10 Jun 2021 09:18:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

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Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 13:26:05

Generated On: 10 Jun 2021 09:18:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	13:10 (24 HR)
Vital Signs Date and Time (derived)	11 MAR 2021 13:10
Temperature (<i>xxx.x</i>)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3702040

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 13:26:05

Generated On: 10 Jun 2021 09:18:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 MAR 2021

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

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 13:26:05

Generated On: 10 Jun 2021 09:18:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 MAR 2021
Collection time (00:00-23:59)	13:36 (24 HR)
Collection date and time (derived)	11 MAR 2021 13:36

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 21:43:51

Generated On: 10 Jun 2021 09:18:52

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

AEID

Adverse event

JOINT PAIN (EDIARY)

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

25 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input 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	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

AEID

Adverse event

URINARY HESITANCY

Was this a medically-attended AE?

Yes ☒
No ☐

Was this a Solicited Adverse Reaction?

Yes ☐
No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐
No ☒

Start date (dd MMM yyyy)

01 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒
No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

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

Is the adverse event serious?

Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity False

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

AEID	
Adverse event	UNKNOWN REPRODUCTIVE SYSTEM DISORDER (ELEVATED PSA)
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

AEID	USA-US133-2021-MRNA-1273-P30 1000004
Adverse event	PROSTATE CANCER
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)	26 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

59 YEAR OLD AFRICAN
AMERICAN MALE SOUGHT OUT
A UROLOGY CONSULT AFTER
AN ELEVATED PSA RESULT ON
ROUTINE SCREENING
(RESULTS BELOW) IN
ADDITIONAL TO NEW ONSET
FREQUENCY AND NOCTURIA.
HE HAS A (b) (6) FAMILY
HISTORY OF PROSTATE
CANCER.

A RADIOLOGICAL WORK-UP
WAS SUPPORTIVE OF THE
CONFIRMED BIOPSY FINDING
26 JAN 2021 OF PROSTATE
ADENOCARCINOMA (GLEASON
STAGE 9). HE IS SCHEDULED TO
HAVE A COMPLETE RADICAL
PROSTATECTOMY IN APR 2021.

ON 5 FEB 2021 HE STARTED
FIRMAGON 120MG, SINGLE SC
COURSE, TO BE FOLLOWED BY
LUPRON INJECTIONS IN MAR
2021.

HIS BONE SCAN 1 FEB 2021
FOUND NO EVIDENCE OF
METASTASIS.

PSA VALUES
1/5/2020 54
1/1/2020 56.03

ADDITIONAL RADIOLOGICAL

US3702040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

SUMMARY:

CT ABDOMEN PELVIS WITH
AND WITHOUT IV CONTRAST 1
FEB 2021

IMPRESSION:

ASYMMETRICALLY ENLARGED
PROSTATE GLAND. NORMAL
BLADDER AND UPPER TRACTS.
GALLSTONES

MRI PROSTATE WITH AND
WITHOUT IV CONTRAST 16 JAN
2021

39 X 33 MM PREDOMINANTLY
LEFT (CROSSING INTO RIGHT)
THROUGHOUT TRANSVERSE
PLANE MIDGLAND
(EXTENDING FROM BASE TO
APEX) TRANSITION ZONE
LESION. PI-RADS 5, VERY HIGH
(CLINICALLY SIGNIFICANT
CANCER HIGHLY LIKELY).

16 X 9 MM LEFT ANTERIOR
BASE (EXTENDING TO
MIDGLAND) PERIPHERAL ZONE
LESION. PI-RADS 5, VERY HIGH
(CLINICALLY SIGNIFICANT
CANCER HIGHLY LIKELY).

27 X 22 MM LEFT
POSTEROMEDIAL BASE
CENTRAL LESION. PI-RADS 5,
VERY HIGH (CLINICALLY
SIGNIFICANT CANCER HIGHLY
LIKELY).

US3702040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

THERE IS OVERLYING GROSS
EXTRAPROSTATIC EXTENSION
INTO THE LEFT SEMINAL
VESICLE.

NO PELVIC
LYMPHADENOPATHY.

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)	
--	--

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

AEID

Adverse event

FEVER (100.2 F)

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

09 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

09 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Apr 2021 13:26:05

Generated On: 10 Jun 2021 09:18:52

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

Yes ☒

No ☐

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

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 13:26:04

Generated On: 10 Jun 2021 09:18:52

Name of Medication CHOLECALCIFEROL

Prophylaxis Yes ☐
No ☒

Indication VITAMIN DEFICIENCY

Dose per administration 125

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 13:26:04

Generated On: 10 Jun 2021 09:18:52

	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)	01 JAN 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 13:26:04

Generated On: 10 Jun 2021 09:18:52

Name of Medication SEMAGLUTIDE

Prophylaxis Yes ☐
No ☒

Indication OBESITY

Dose per administration 0.25 OR 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 13:26:04

Generated On: 10 Jun 2021 09:18:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 13:26:04

Generated On: 10 Jun 2021 09:18:52

Name of Medication VILAZODONE HCL

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 13:26:04

Generated On: 10 Jun 2021 09:18:52

	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)		01 JAN 2019
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 13:26:04

Generated On: 10 Jun 2021 09:18:52

Name of Medication CIALIS

Prophylaxis Yes ☐
No ☒

Indication URINARY HESITANCY

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 13:26:04

Generated On: 10 Jun 2021 09:18:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 13:26:04

Generated On: 10 Jun 2021 09:18:52

Name of Medication AMOXICILLIN

Prophylaxis Yes ☒
No ☐

Indication ORAL SURGERY PROPHYLAXIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 13:26:04

Generated On: 10 Jun 2021 09:18:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 13:26:04

Generated On: 10 Jun 2021 09:18:52

Name of Medication DEGARELIX (FIRMAGON)

Prophylaxis Yes ☐
No ☒

Indication PROSTATE CANCER

Dose per administration 120

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 13:26:04

Generated On: 10 Jun 2021 09:18:52

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		05 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 13:26:04

Generated On: 10 Jun 2021 09:18:52

Name of Medication MOTRIN

Prophylaxis Yes ☐
No ☒

Indication FEVER

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 13:26:04

Generated On: 10 Jun 2021 09:18:52

	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)		09 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 09 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 13:26:04

Generated On: 10 Jun 2021 09:18:52

Name of Medication LEUPROLIDE ACETATE
(ELIGARD) INJECTION

Prophylaxis Yes ☐
No ☒

Indication PROSTATE CANCER

Dose per administration 22.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 13:26:04

Generated On: 10 Jun 2021 09:18:52

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	05 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3702040

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Apr 2021 13:26:05

Generated On: 10 Jun 2021 09:18:52

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 10 Jun 2021 09:18:52

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
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US3702040

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:18:52

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

US3702040

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:18:52

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 ☐

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 13:28:47

Generated On: 10 Jun 2021 09:18:52

SAEID	USA-US133-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	KRISTEN
Investigator's Last Name	MARKS
Site Address: Street	525 EAST 68TH STREET
Site Address: City	NEW YORK
Site Address: State	NY
Site Address: Postal Code	10065
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 13:28:47

Generated On: 10 Jun 2021 09:18:52

SAEID	USA-US133-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	KRISTEN
Investigator's Last Name	MARKS
Site Address: Street	525 EAST 68TH STREET
Site Address: City	NEW YORK
Site Address: State	NY
Site Address: Postal Code	10065
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	09/MAR/2021 08:49
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

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 13:28:47

Generated On: 10 Jun 2021 09:18:52

SAEID	USA-US133-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	KRISTEN
Investigator's Last Name	MARKS
Site Address: Street	525 EAST 68TH STREET
Site Address: City	NEW YORK
Site Address: State	NY
Site Address: Postal Code	10065
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	31/MAR/2021 10:21
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.	True

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 13:28:47

Generated On: 10 Jun 2021 09:18:52

SAEID	USA-US133-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	KRISTEN
Investigator's Last Name	MARKS
Site Address: Street	525 EAST 68TH STREET
Site Address: City	NEW YORK
Site Address: State	NY
Site Address: Postal Code	10065
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	14/APR/2021 13:40
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

US3702040 (Prod: Weill Cornell Chelsea - (CRS))

US3702040

Form: Participant Creation

Generated On: 10 Jun 2021 09:18:52

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 13:26:05
User entered 'US3702040'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	21 Sep 2020 13:40:48

US3702040

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Caique Mello (b) (4)	21 Sep 2020 14:27:37

US3702040

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	25 Sep 2020 18:21:27
User entered '21 Sep 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	25 Sep 2020 18:21:27
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	25 Sep 2020 18:21:20
User entered '14 Sep 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	25 Sep 2020 18:21:20
User entered '21 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 13:40:49

US3702040

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

[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 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Jiamin Li (b) (4)	25 Sep 2020 18:21:27
User entered 'Home (Home)' reason for change: Data Entry Error	Jiamin Li (b) (4)	25 Sep 2020 18:21:20
User entered 'Clinic (Clinic)'	Caique Mello (b) (4)	21 Sep 2020 14:27:37

US3702040

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'SCRN'	System	21 Sep 2020 14:27:37

US3702040

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:52

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered (b) (6) 1961'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 13:40:50

US3702040

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:52

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '58'	Jiamin Li (b) (4)	25 Sep 2020 18:13:04

US3702040

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:52

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'YEARS'	System	25 Sep 2020 18:13:04

US3702040

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:52

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered '59'	System	21 Sep 2020 14:28:03

US3702040

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:52

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User closed query 'Per CDM: Please complete this form. Enter Sex, Ethnicity and Race.	(b) (4), (b) (6)	25 Sep 2020 18:18:46
' (Site from DM). Query 'Per CDM: Please complete this form. Enter Sex, Ethnicity and Race.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:13:49
' answered with 'Done' (Site from DM). User entered 'Male (M)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:13:04
User opened query 'Per CDM: Please complete this form. Enter Sex, Ethnicity and Race.	(b) (4), (b) (6)	22 Sep 2020 13:56:54
' (Site from DM).		

US3702040

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:52

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Jiamin Li (b) (4)	25 Sep 2020 18:13:04

US3702040

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:52

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 18:13:04

US3702040

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:52

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'I'	Jiamin Li (b) (4)	25 Sep 2020 18:13:04

US3702040

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:52

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 18:13:04

US3702040

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:52

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 18:13:04

US3702040

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:52

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 18:13:04

US3702040

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:52

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 18:13:04

US3702040

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:52

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 18:13:04

US3702040

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:52

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 18:13:04

US3702040

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:52

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 18:13:04

US3702040

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:18:52

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '21 Sep 2020'	Caique Mello (b) (4)	21 Sep 2020 14:28:03

US3702040

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'Sep 2020'	System	21 Sep 2020 14:28:03

US3702040

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered '2020'	System	21 Sep 2020 14:28:03

US3702040

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:18:52

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Amendment 3 (3)'	Caique Mello (b) (4)	21 Sep 2020 14:28:03

US3702040

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Caique Mello (b) (4)	21 Sep 2020 14:28:03

US3702040

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Caique Mello (b) (4)	21 Sep 2020 14:28:03

US3702040

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:18:52

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Caique Mello (b) (4)	21 Sep 2020 14:28:03

US3702040

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:18:52

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Caique Mello (b) (4)	21 Sep 2020 14:28:03

US3702040

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:18:52

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 13:40:49

US3702040

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:18:52

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'I'	System	21 Sep 2020 14:28:09

US3702040

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Caique Mello (b) (4)	21 Sep 2020 14:28:09

US3702040

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:18:52

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Sep 2020 18:15:02

US3702040

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:18:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Gun shot wound, LLT: Gun shot wound - version MedDRA\\23.0.	Coder Import (b) (4)	26 Sep 2020 05:53:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	26 Sep 2020 05:53:40
Data point term sent to Coder	System	25 Sep 2020 18:16:08
User entered 'Gun shot wound of chest cavity'	Jiamin Li (b) (4)	25 Sep 2020 18:15:17

US3702040

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'un UNK 1967'	Jiamin Li (b) (4)	25 Sep 2020 18:15:17

US3702040

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:18:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 18:15:17

US3702040

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:18:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Sep 2020 18:15:17

US3702040

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 18:15:17

US3702040

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:18:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 18:15:17

US3702040

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'Jan 1967'	System	25 Sep 2020 18:15:17

US3702040

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered '1967'	System	25 Sep 2020 18:15:17

US3702040

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered empty.	System	25 Sep 2020 18:15:17

US3702040

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered empty.	System	25 Sep 2020 18:15:17

US3702040

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:18:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
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)	25 Sep 2020 18:16:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 18:16:50
Data point term sent to Coder	System	25 Sep 2020 18:16:08
User entered 'Depression'	Jiamin Li (b) (4)	25 Sep 2020 18:15:24

US3702040

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'un UNK 2019'	Jiamin Li (b) (4)	25 Sep 2020 18:15:24

US3702040

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:18:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 18:15:24

US3702040

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:18:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Sep 2020 18:15:24

US3702040

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 18:15:24

US3702040

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:18:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 18:15:24

US3702040

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'Jan 2019'	System	25 Sep 2020 18:15:24

US3702040

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered '2019'	System	25 Sep 2020 18:15:24

US3702040

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered empty.	System	25 Sep 2020 18:15:24

US3702040

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered empty.	System	25 Sep 2020 18:15:24

US3702040

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:18:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 18:16:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 18:16:50
Data point term sent to Coder	System	25 Sep 2020 18:16:08
User entered 'Obesity'	Jiamin Li (b) (4)	25 Sep 2020 18:15:31

US3702040

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'un UNK 2019'	Jiamin Li (b) (4)	25 Sep 2020 18:15:31

US3702040

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:18:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 18:15:31

US3702040

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:18:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Sep 2020 18:15:31

US3702040

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 18:15:31

US3702040

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:18:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 18:15:31

US3702040

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'Jan 2019'	System	25 Sep 2020 18:15:31

US3702040

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered '2019'	System	25 Sep 2020 18:15:31

US3702040

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered empty.	System	25 Sep 2020 18:15:31

US3702040

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered empty.	System	25 Sep 2020 18:15:31

US3702040

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:18:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 18:16:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 18:16:50
Data point term sent to Coder	System	25 Sep 2020 18:16:09
User entered 'Gastroesophageal reflux disease'	Jiamin Li (b) (4)	25 Sep 2020 18:15:43

US3702040

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'un UNK 2011'	Jiamin Li (b) (4)	25 Sep 2020 18:15:43

US3702040

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:18:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 18:15:43

US3702040

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:18:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Sep 2020 18:15:43

US3702040

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 18:15:43

US3702040

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:18:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 18:15:43

US3702040

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'Jan 2011'	System	25 Sep 2020 18:15:43

US3702040

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered '2011'	System	25 Sep 2020 18:15:43

US3702040

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered empty.	System	25 Sep 2020 18:15:43

US3702040

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered empty.	System	25 Sep 2020 18:15:43

US3702040

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:18:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Facial pain, LLT: Facial pain - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 18:22:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 18:22:47
Data point term sent to Coder	System	25 Sep 2020 18:21:25
User entered 'Facial pain'	Jiamin Li (b) (4)	25 Sep 2020 18:20:45

US3702040

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '31 Aug 2020'	Jiamin Li (b) (4)	25 Sep 2020 18:20:45

US3702040

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:18:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 18:20:45

US3702040

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:18:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Sep 2020 18:20:45

US3702040

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 18:20:45

US3702040

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:18:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 18:20:45

US3702040

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'Aug 2020'	System	25 Sep 2020 18:20:45

US3702040

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered '2020'	System	25 Sep 2020 18:20:45

US3702040

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered empty.	System	25 Sep 2020 18:20:45

US3702040

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered empty.	System	25 Sep 2020 18:20:45

US3702040

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:18:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Dermal filler injection, LLT: Dermal filler injection - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 07:56:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 07:56:01
Data point term sent to Coder	System	13 Apr 2021 16:29:11
User entered 'Botox (forehead)'	Jiamin Li (b) (4)	13 Apr 2021 16:28:31

US3702040

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered 'un Jan 2020'	Jiamin Li (b) (4)	13 Apr 2021 16:28:31

US3702040

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:18:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered '0'	Jiamin Li (b) (4)	13 Apr 2021 16:28:31

US3702040

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:18:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered 'No (N)'	Jiamin Li (b) (4)	13 Apr 2021 16:28:31

US3702040

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered empty.	Jiamin Li (b) (4)	13 Apr 2021 16:28:31

US3702040

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:18:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered 'I'	Jiamin Li (b) (4)	13 Apr 2021 16:28:31

US3702040

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'Jan 2020'	System	13 Apr 2021 16:28:31

US3702040

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered '2020'	System	13 Apr 2021 16:28:31

US3702040

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered empty.	System	13 Apr 2021 16:28:31

US3702040

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered empty.	System	13 Apr 2021 16:28:31

US3702040

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	25 Sep 2020 18:22:25
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 18:14:36

US3702040

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '21 Sep 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	25 Sep 2020 18:22:25
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 18:14:36

US3702040

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '09:30' reason for change: Data Entry Error	Jiamin Li (b) (4)	25 Sep 2020 18:22:25
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 18:14:36

US3702040

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered '21 Sep 2020 09:30'	System	25 Sep 2020 18:22:25
User entered empty.	System	25 Sep 2020 18:14:36

US3702040

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '168' cm reason for change: Data Entry Error	Jiamin Li (b) (4)	25 Sep 2020 18:22:25
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 18:14:36
DataPoint set to visible.	System	21 Sep 2020 14:28:09

US3702040

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '85.4' kg reason for change: Data Entry Error	Jiamin Li (b) (4)	25 Sep 2020 18:22:25
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 18:14:36
DataPoint set to visible.	System	21 Sep 2020 14:28:09

US3702040

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered '30.25794'	System	25 Sep 2020 18:22:25
User entered empty.	System	25 Sep 2020 18:14:36
DataPoint set to visible.	System	21 Sep 2020 14:28:09

US3702040

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'kg/m2'	System	25 Sep 2020 18:22:25
User entered empty.	System	25 Sep 2020 18:14:36
DataPoint set to visible.	System	21 Sep 2020 14:28:09

US3702040

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Jiamin Li (b) (4)	25 Sep 2020 18:22:25
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 18:14:36

US3702040

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 18:14:36

US3702040

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 18:14:36

US3702040

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Jiamin Li (b) (4)	25 Sep 2020 18:22:25
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 18:14:36

US3702040

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'bpm'	System	25 Sep 2020 18:22:25
User entered empty.	System	25 Sep 2020 18:14:36

US3702040

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Jiamin Li (b) (4)	25 Sep 2020 18:22:25
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 18:14:36

US3702040

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'breaths/min'	System	25 Sep 2020 18:22:25
User entered empty.	System	25 Sep 2020 18:14:36

US3702040

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Jiamin Li (b) (4)	25 Sep 2020 18:22:25
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 18:14:36

US3702040

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'mmHg'	System	25 Sep 2020 18:22:25
User entered empty.	System	25 Sep 2020 18:14:36

US3702040

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Jiamin Li (b) (4)	25 Sep 2020 18:22:25
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 18:14:36

US3702040

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'mmHg'	System	25 Sep 2020 18:22:25
User entered empty.	System	25 Sep 2020 18:14:36

US3702040

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04

US3702040

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	25 Sep 2020 18:22:33
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 18:14:44

US3702040

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '21 Sep 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	25 Sep 2020 18:22:33
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 18:14:44

US3702040

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:52

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 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Sep 2020 18:14:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:52

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 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 18:14:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:52

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 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 18:14:22

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Folder: Screening

Form: Risk of Exposure

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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 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 18:14:22

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Folder: Screening

Form: Risk of Exposure

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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 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 18:14:22

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Folder: Screening

Form: Risk of Exposure

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[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 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 18:14:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:52

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 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 18:14:22

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Folder: Screening

Form: Risk of Exposure

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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 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 18:14:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:52

[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 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 18:14:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:52

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 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 18:14:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:52

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 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 18:14:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:52

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 18:14:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:52

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 18:14:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:52

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User closed query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	System	29 Sep 2020 14:25:14
User entered '0' reason for change: Data Entry Error	Jiamin Li (b) (4)	29 Sep 2020 14:25:14
User opened query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	System	25 Sep 2020 18:24:03
User entered '1'	Jiamin Li (b) (4)	25 Sep 2020 18:14:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 18:14:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:52

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 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 18:14:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:52

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 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 18:14:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:52

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 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 18:14:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 18:14:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:52

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '1' reason for change: Data Entry Error	Jiamin Li (b) (4)	25 Sep 2020 18:24:03
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 18:14:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:52

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Use of MTA' reason for change: Data Entry Error	Jiamin Li (b) (4)	25 Sep 2020 18:24:03
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 18:14:22

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Sep 2020 18:22:40

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '21 Sep 2020'	Jiamin Li (b) (4)	25 Sep 2020 18:22:40

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Clinic (Clinic)'	Jiamin Li (b) (4)	25 Sep 2020 18:22:40

US3702040

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User entered 'VISIT1'	System	25 Sep 2020 18:22:40

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '21 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 14:10:32

US3702040

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '145184'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 14:10:32

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
Query 'Per CDM: Cohort has been updated as at risk, but none of them are checked in the checklist provided. Please review and update accordingly' canceled (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 14:12:11
User opened query 'Per CDM: Cohort has been updated as at risk, but none of them are checked in the checklist provided. Please review and update accordingly' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 21:26:00
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	01 Oct 2020 19:19:22
Amendment Manager: User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	30 Sep 2020 22:36:59
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		30 Sep 2020 22:36:58
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' answered with 'This is a randomization error, participant is considered as being in the <65y low risk cohort. Please provide guidance on how to alter this in the system.' (Site from System).	Jiamin Li (b) (4)	29 Sep 2020 14:46:38
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	25 Sep 2020 18:24:14
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 14:10:32

US3702040

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 18:24:14

US3702040

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 18:24:14

US3702040

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 18:24:14

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 18:24:14

US3702040

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:18:52

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 18:24:14

US3702040

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:18:52

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 18:24:14
DataPoint set to visible.	System	21 Sep 2020 14:28:03

US3702040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:18:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	25 Sep 2020 18:23:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:18:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	25 Sep 2020 18:23:23

US3702040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:18:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	25 Sep 2020 18:23:23

US3702040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:18:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	25 Sep 2020 18:23:23

US3702040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User accepted default value 'Pre-Dose (PREDOSE)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:23:23

US3702040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Sep 2020 18:23:23

US3702040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '21 Sep 2020'	Jiamin Li (b) (4)	25 Sep 2020 18:23:23

US3702040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '09:30'	Jiamin Li (b) (4)	25 Sep 2020 18:23:23

US3702040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User entered '21 Sep 2020 09:30'	System	25 Sep 2020 18:23:23

US3702040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '36.3' C	Jiamin Li (b) (4)	25 Sep 2020 18:23:23

US3702040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Other (Other)'	Jiamin Li (b) (4)	25 Sep 2020 18:23:23

US3702040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Temporal'	Jiamin Li (b) (4)	25 Sep 2020 18:23:23

US3702040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '72'	Jiamin Li (b) (4)	25 Sep 2020 18:23:23

US3702040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User entered 'bpm'	System	25 Sep 2020 18:23:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '16'	Jiamin Li (b) (4)	25 Sep 2020 18:23:23

US3702040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User entered 'breaths/min'	System	25 Sep 2020 18:23:23

US3702040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '119'	Jiamin Li (b) (4)	25 Sep 2020 18:23:23

US3702040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User entered 'mmHg'	System	25 Sep 2020 18:23:23

US3702040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '84'	Jiamin Li (b) (4)	25 Sep 2020 18:23:23

US3702040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User entered 'mmHg'	System	25 Sep 2020 18:23:23

US3702040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:18:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	25 Sep 2020 18:23:23

US3702040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:18:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	25 Sep 2020 18:23:23

US3702040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User accepted default value 'Post-Dose (POSTDOSE)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:23:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Sep 2020 18:23:23

US3702040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '21 Sep 2020'	Jiamin Li (b) (4)	25 Sep 2020 18:23:23

US3702040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '12:00'	Jiamin Li (b) (4)	25 Sep 2020 18:23:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User entered '21 Sep 2020 12:00'	System	25 Sep 2020 18:23:23

US3702040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '36.8' C	Jiamin Li (b) (4)	25 Sep 2020 18:23:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Oral (Oral)'	Jiamin Li (b) (4)	25 Sep 2020 18:23:23

US3702040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 18:23:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '66'	Jiamin Li (b) (4)	25 Sep 2020 18:23:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User entered 'bpm'	System	25 Sep 2020 18:23:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '16'	Jiamin Li (b) (4)	25 Sep 2020 18:23:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User entered 'breaths/min'	System	25 Sep 2020 18:23:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '125'	Jiamin Li (b) (4)	25 Sep 2020 18:23:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User entered 'mmHg'	System	25 Sep 2020 18:23:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '82'	Jiamin Li (b) (4)	25 Sep 2020 18:23:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User entered 'mmHg'	System	25 Sep 2020 18:23:23

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 18:23:28

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 18:23:28

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User closed query 'Per CDM: Please complete Visit Date Form for Visit 1 Day 1.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 13:20:59
Query 'Per CDM: Please complete Visit Date Form for Visit 1 Day 1.' answered with 'Done' (Site from DM).	Jiamin Li (b) (4)	25 Sep 2020 18:25:26
User opened query 'Per CDM: Please complete Visit Date Form for Visit 1 Day 1.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 18:43:19
User entered 'Yes (Y)'	Caique Mello (b) (4)	21 Sep 2020 15:33:55

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Caique Mello (b) (4)	21 Sep 2020 15:33:55

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Folder: Visit 1 Day 1

Form: Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Caique Mello (b) (4)	21 Sep 2020 15:33:55

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 15:33:55

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '21 Sep 2020'	Caique Mello (b) (4)	21 Sep 2020 15:33:55

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '11:29'	Caique Mello (b) (4)	21 Sep 2020 15:33:55

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User entered '21 Sep 2020 11:29'	System	21 Sep 2020 15:33:55

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Left Arm (LEFT ARM)'	Caique Mello (b) (4)	21 Sep 2020 15:33:55

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User entered 'ONCE'	System	21 Sep 2020 15:33:55

US3702040

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 15:33:55

US3702040

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Sep 2020 20:16:40

US3702040

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '21 Sep 2020'	Jiamin Li (b) (4)	25 Sep 2020 20:16:40

US3702040

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:52

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '10:15'	Jiamin Li (b) (4)	25 Sep 2020 20:16:40

US3702040

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User entered '21 Sep 2020 10:15'	System	25 Sep 2020 20:16:40

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '21 Sep 2020'	Jiamin Li (b) (4)	25 Sep 2020 18:25:12

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:18:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:25:12

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:18:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Sep 2020 18:25:12

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:18:52

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '10:25'	Jiamin Li (b) (4)	25 Sep 2020 18:25:12

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User entered '21 Sep 2020 10:25'	System	25 Sep 2020 18:25:12

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:18:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:25:12

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:18:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 18:25:12

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:18:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 18:25:12

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User entered empty.	System	25 Sep 2020 18:25:12

US3702040

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Sep 2020 18:25:16

US3702040

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User entered 'I'	System	25 Sep 2020 18:25:16

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	21 Sep 2020 15:33:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T11:57:29', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'a48158fd-f97e-4930-879b-a95cae77c931' User entered 'Yes (Y)'	System	21 Sep 2020 16:03:09
	System	21 Sep 2020 16:03:09

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T11:59:56', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'a48158fd-f97e-4930-879b-a95cae77c931' User entered '98.6'	System	21 Sep 2020 16:03:09
	System	21 Sep 2020 16:03:09

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T12:00:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'a48158fd-f97e-4930-879b-a95cae77c931' User entered 'No (N)'	System	21 Sep 2020 16:03:09
	System	21 Sep 2020 16:03:09

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T12:00:07', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'a48158fd-f97e-4930-879b-a95cae77c931' User entered '21 Sep 2020 12:00'	System	21 Sep 2020 16:03:09
	System	21 Sep 2020 16:03:09

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '21 Sep 2020 11:49'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '21 Sep 2020 14:19'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	21 Sep 2020 15:33:55
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T17:43:25', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '316dc05b-6e31-4f0f-a54e-65fae542ae57' User entered 'Yes (Y)'	System	21 Sep 2020 21:43:39
	System	21 Sep 2020 21:43:39

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T17:43:31', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '316dc05b-6e31-4f0f-a54e-65fae542ae57' User entered '98.0'	System	21 Sep 2020 21:43:39
	System	21 Sep 2020 21:43:39

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T17:43:34', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '316dc05b-6e31-4f0f-a54e-65fae542ae57'	System	21 Sep 2020 21:43:39
User entered 'No (N)'	System	21 Sep 2020 21:43:39

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T17:43:37', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '316dc05b-6e31-4f0f-a54e-65fae542ae57' User entered '21 Sep 2020 17:43'	System	21 Sep 2020 21:43:39
	System	21 Sep 2020 21:43:39

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '21 Sep 2020 15:14'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	21 Sep 2020 15:33:55
User entered 'Day 2'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-22T19:28:48', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'd0ce99e1-e64e-46b2-87a4-7e75dcf1c423' User entered 'Yes (Y)'	System	22 Sep 2020 23:29:04
	System	22 Sep 2020 23:29:04

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-22T19:28:52', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'd0ce99e1-e64e-46b2-87a4-7e75dcf1c423' User entered '99.0'	System	22 Sep 2020 23:29:04
	System	22 Sep 2020 23:29:04

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-22T19:28:56', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'd0ce99e1-e64e-46b2-87a4-7e75dcf1c423'	System	22 Sep 2020 23:29:04
User entered 'No (N)'	System	22 Sep 2020 23:29:04

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-22T19:28:59', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'd0ce99e1-e64e-46b2-87a4-7e75dcf1c423' User entered '22 Sep 2020 19:28'	System	22 Sep 2020 23:29:04
	System	22 Sep 2020 23:29:04

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	21 Sep 2020 15:33:55
User entered 'Day 3'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-23T16:53:12', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '5af7296f-208d-4ac5-bcf8-8de2e927d0a3' User entered 'Yes (Y)'	System	23 Sep 2020 20:53:31
	System	23 Sep 2020 20:53:31

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-23T16:53:20', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '5af7296f-208d-4ac5-bcf8-8de2e927d0a3' User entered '99.1'	System	23 Sep 2020 20:53:31
	System	23 Sep 2020 20:53:31

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-23T16:53:23', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '5af7296f-208d-4ac5-bcf8-8de2e927d0a3'	System	23 Sep 2020 20:53:31
User entered 'No (N)'	System	23 Sep 2020 20:53:31

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-23T16:53:26', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '5af7296f-208d-4ac5-bcf8-8de2e927d0a3' User entered '23 Sep 2020 16:53'	System	23 Sep 2020 20:53:31
	System	23 Sep 2020 20:53:31

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	21 Sep 2020 15:33:55
User entered 'Day 4'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-24T18:19:14', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '0d903219-6cb8-4f86-8012-0caf956e2cf8'	System	24 Sep 2020 22:19:30
User entered 'Yes (Y)'	System	24 Sep 2020 22:19:30

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-24T18:19:18', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '0d903219-6cb8-4f86-8012-0caf956e2cf8' User entered '98.9'	System	24 Sep 2020 22:19:30
	System	24 Sep 2020 22:19:30

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-24T18:19:21', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '0d903219-6cb8-4f86-8012-0caf956e2cf8'	System	24 Sep 2020 22:19:30
User entered 'No (N)'	System	24 Sep 2020 22:19:30

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-24T18:19:24', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '0d903219-6cb8-4f86-8012-0caf956e2cf8'	System	24 Sep 2020 22:19:30
User entered '24 Sep 2020 18:19'	System	24 Sep 2020 22:19:30

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	21 Sep 2020 15:33:55
User entered 'Day 5'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T00:30:05', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '12c66dc1-8ddb-41b2-a43c-a474b4028632' User entered 'Yes (Y)'	System	26 Sep 2020 04:30:16
	System	26 Sep 2020 04:30:16

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T00:30:09', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '12c66dc1-8ddb-41b2-a43c-a474b4028632' User entered '99.1'	System	26 Sep 2020 04:30:16
	System	26 Sep 2020 04:30:16

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T00:30:12', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '12c66dc1-8ddb-41b2-a43c-a474b4028632'	System	26 Sep 2020 04:30:16
User entered 'No (N)'	System	26 Sep 2020 04:30:16

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T00:30:14', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '12c66dc1-8ddb-41b2-a43c-a474b4028632' User entered '26 Sep 2020 00:30'	System	26 Sep 2020 04:30:16
	System	26 Sep 2020 04:30:16

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	21 Sep 2020 15:33:55
User entered 'Day 6'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T16:37:49', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '5c672c24-7700-4445-95cd-87672627f1fa' User entered 'Yes (Y)'	System	26 Sep 2020 20:38:06
	System	26 Sep 2020 20:38:06

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T16:37:55', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '5c672c24-7700-4445-95cd-87672627f1fa' User entered '99.0'	System	26 Sep 2020 20:38:06
	System	26 Sep 2020 20:38:06

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T16:37:58', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '5c672c24-7700-4445-95cd-87672627f1fa' User entered 'No (N)'	System	26 Sep 2020 20:38:06
	System	26 Sep 2020 20:38:06

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T16:38:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '5c672c24-7700-4445-95cd-87672627f1fa' User entered '26 Sep 2020 16:38'	System	26 Sep 2020 20:38:06
	System	26 Sep 2020 20:38:06

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	21 Sep 2020 15:33:55
User entered 'Day 7'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-28T05:47:07', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '83f9301e-081e-4364-8358-47d94dace1c2' User entered 'Yes (Y)'	System	28 Sep 2020 09:47:27
	System	28 Sep 2020 09:47:27

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-28T05:47:17', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '83f9301e-081e-4364-8358-47d94dace1c2' User entered '98.1'	System	28 Sep 2020 09:47:27
	System	28 Sep 2020 09:47:27

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-28T05:47:20', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '83f9301e-081e-4364-8358-47d94dace1c2'	System	28 Sep 2020 09:47:27
User entered 'No (N)'	System	28 Sep 2020 09:47:27

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-28T05:47:23', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '83f9301e-081e-4364-8358-47d94dace1c2' User entered '28 Sep 2020 05:47'	System	28 Sep 2020 09:47:27
	System	28 Sep 2020 09:47:27

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	21 Sep 2020 15:33:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T12:00:18', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '90ffb98a-b8c0-4015-bd14-cf776794703f' User entered 'None (1)'	System	21 Sep 2020 16:04:24
	System	21 Sep 2020 16:04:24

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T12:00:47', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '90ffb98a-b8c0-4015-bd14-cf776794703f' User entered 'No (N)'	System	21 Sep 2020 16:04:24
	System	21 Sep 2020 16:04:24

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T12:00:52', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '90ffb98a-b8c0-4015-bd14-cf776794703f' User entered 'No (N)'	System	21 Sep 2020 16:04:24
	System	21 Sep 2020 16:04:24

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T12:00:58', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '90ffb98a-b8c0-4015-bd14-cf776794703f' User entered 'None (1)'	System	21 Sep 2020 16:04:24
	System	21 Sep 2020 16:04:24

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T12:01:01', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '90ffb98a-b8c0-4015-bd14-cf776794703f' User entered '21 Sep 2020 12:01'	System	21 Sep 2020 16:04:24
	System	21 Sep 2020 16:04:24

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '21 Sep 2020 11:49'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '21 Sep 2020 14:19'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	21 Sep 2020 15:33:55
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T17:43:48', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '598f0f87-59da-4403-8b77-8aeaa068c62d' User entered 'None (1)'	System	21 Sep 2020 21:44:06
	System	21 Sep 2020 21:44:06

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T17:43:52', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '598f0f87-59da-4403-8b77-8aeaa068c62d' User entered 'No (N)'	System	21 Sep 2020 21:44:06
	System	21 Sep 2020 21:44:06

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T17:43:55', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '598f0f87-59da-4403-8b77-8aeaa068c62d' User entered 'No (N)'	System	21 Sep 2020 21:44:06
	System	21 Sep 2020 21:44:06

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T17:43:58', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '598f0f87-59da-4403-8b77-8aeaa068c62d' User entered 'None (1)'	System	21 Sep 2020 21:44:06
	System	21 Sep 2020 21:44:06

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T17:44:03', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '598f0f87-59da-4403-8b77-8aeaa068c62d' User entered '21 Sep 2020 17:44'	System	21 Sep 2020 21:44:06
	System	21 Sep 2020 21:44:06

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '21 Sep 2020 15:14'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	21 Sep 2020 15:33:55
User entered 'Day 2'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-22T19:29:04', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '9dad25ea-f1c1-45ba-b298-0000aa9132bd' User entered 'None (1)'	System	22 Sep 2020 23:29:55
	System	22 Sep 2020 23:29:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-22T19:29:08', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '9dad25ea-f1c1-45ba-b298-0000aa9132bd' User entered 'No (N)'	System	22 Sep 2020 23:29:55
	System	22 Sep 2020 23:29:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-22T19:29:10', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '9dad25ea-f1c1-45ba-b298-0000aa9132bd' User entered 'No (N)'	System	22 Sep 2020 23:29:55
	System	22 Sep 2020 23:29:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-22T19:29:14', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '9dad25ea-f1c1-45ba-b298-0000aa9132bd' User entered 'None (1)'	System	22 Sep 2020 23:29:55
	System	22 Sep 2020 23:29:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-22T19:29:16', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '9dad25ea-f1c1-45ba-b298-0000aa9132bd' User entered '22 Sep 2020 19:29'	System	22 Sep 2020 23:29:55
	System	22 Sep 2020 23:29:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	21 Sep 2020 15:33:55
User entered 'Day 3'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-23T16:53:34', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '00ffd819-501f-46c2-80af-000f77f6c770'	System	23 Sep 2020 20:53:49
User entered 'None (1)'	System	23 Sep 2020 20:53:49

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-23T16:53:37', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '00ffd819-501f-46c2-80af-000f77f6c770'	System	23 Sep 2020 20:53:49
User entered 'No (N)'	System	23 Sep 2020 20:53:49

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-23T16:53:42', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '00ffd819-501f-46c2-80af-000f77f6c770' User entered 'No (N)'	System	23 Sep 2020 20:53:49
	System	23 Sep 2020 20:53:49

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-23T16:53:44', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '00ffd819-501f-46c2-80af-000f77f6c770' User entered 'None (1)'	System	23 Sep 2020 20:53:49
	System	23 Sep 2020 20:53:49

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-23T16:53:46', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '00ffd819-501f-46c2-80af-000f77f6c770' User entered '23 Sep 2020 16:53'	System	23 Sep 2020 20:53:49
	System	23 Sep 2020 20:53:49

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	21 Sep 2020 15:33:55
User entered 'Day 4'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-24T18:19:29', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '312a3572-8481-47f1-9de0-87018a6055c3' User entered 'None (1)'	System	24 Sep 2020 22:19:40
	System	24 Sep 2020 22:19:40

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-24T18:19:32', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '312a3572-8481-47f1-9de0-87018a6055c3' User entered 'No (N)'	System	24 Sep 2020 22:19:40
	System	24 Sep 2020 22:19:40

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-24T18:19:34', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '312a3572-8481-47f1-9de0-87018a6055c3' User entered 'No (N)'	System	24 Sep 2020 22:19:40
	System	24 Sep 2020 22:19:40

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-24T18:19:36', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '312a3572-8481-47f1-9de0-87018a6055c3' User entered 'None (1)'	System	24 Sep 2020 22:19:40
	System	24 Sep 2020 22:19:40

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-24T18:19:38', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '312a3572-8481-47f1-9de0-87018a6055c3' User entered '24 Sep 2020 18:19'	System	24 Sep 2020 22:19:40
	System	24 Sep 2020 22:19:40

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	21 Sep 2020 15:33:55
User entered 'Day 5'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T00:30:18', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '1eeda040-41d8-42e2-b084-454509cfc8c8' User entered 'None (1)'	System	26 Sep 2020 04:30:33
	System	26 Sep 2020 04:30:33

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T00:30:21', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '1eeda040-41d8-42e2-b084-454509cfc8c8' User entered 'No (N)'	System	26 Sep 2020 04:30:33
	System	26 Sep 2020 04:30:33

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T00:30:23', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '1eeda040-41d8-42e2-b084-454509cfc8c8' User entered 'No (N)'	System	26 Sep 2020 04:30:33
	System	26 Sep 2020 04:30:33

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T00:30:26', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '1eeda040-41d8-42e2-b084-454509cfc8c8'	System	26 Sep 2020 04:30:33
User entered 'None (1)'	System	26 Sep 2020 04:30:33

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T00:30:28', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '1eeda040-41d8-42e2-b084-454509cfc8dc8' User entered '26 Sep 2020 00:30'	System	26 Sep 2020 04:30:33
	System	26 Sep 2020 04:30:33

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	21 Sep 2020 15:33:55
User entered 'Day 6'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T16:38:13', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '7e840e00-d799-4459-bcbb-8c65623dcc83' User entered 'None (1)'	System	26 Sep 2020 20:38:23
	System	26 Sep 2020 20:38:23

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T16:38:09', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '7e840e00-d799-4459-bcbb-8c65623dcc83' User entered 'No (N)'	System	26 Sep 2020 20:38:23
	System	26 Sep 2020 20:38:23

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T16:38:16', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '7e840e00-d799-4459-bcbb-8c65623dcc83' User entered 'No (N)'	System	26 Sep 2020 20:38:23
	System	26 Sep 2020 20:38:23

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T16:38:18', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '7e840e00-d799-4459-bcbb-8c65623dcc83' User entered 'None (1)'	System	26 Sep 2020 20:38:23
	System	26 Sep 2020 20:38:23

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T16:38:20', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '7e840e00-d799-4459-bcbb-8c65623dcc83' User entered '26 Sep 2020 16:38'	System	26 Sep 2020 20:38:23
	System	26 Sep 2020 20:38:23

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	21 Sep 2020 15:33:55
User entered 'Day 7'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-28T05:47:27', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '591f7cfe-a35d-44cd-948a-ac53554963fc' User entered 'None (1)'	System	28 Sep 2020 09:47:41
	System	28 Sep 2020 09:47:41

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-28T05:47:30', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '591f7cfe-a35d-44cd-948a-ac53554963fc' User entered 'No (N)'	System	28 Sep 2020 09:47:41
	System	28 Sep 2020 09:47:41

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-28T05:47:33', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '591f7cfe-a35d-44cd-948a-ac53554963fc' User entered 'No (N)'	System	28 Sep 2020 09:47:41
	System	28 Sep 2020 09:47:41

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-28T05:47:35', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '591f7cfe-a35d-44cd-948a-ac53554963fc' User entered 'None (1)'	System	28 Sep 2020 09:47:41
	System	28 Sep 2020 09:47:41

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-28T05:47:37', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '591f7cfe-a35d-44cd-948a-ac53554963fc' User entered '28 Sep 2020 05:47'	System	28 Sep 2020 09:47:41
	System	28 Sep 2020 09:47:41

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	21 Sep 2020 15:33:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T12:01:07', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '894dd888-c345-4782-95ea-a281ce9125bd' User entered 'None (0)'	System	21 Sep 2020 16:05:22
	System	21 Sep 2020 16:05:22

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T12:01:09', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '894dd888-c345-4782-95ea-a281ce9125bd' User entered 'None (0)'	System	21 Sep 2020 16:05:22
	System	21 Sep 2020 16:05:22

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T12:01:12', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '894dd888-c345-4782-95ea-a281ce9125bd' User entered 'None (0)'	System	21 Sep 2020 16:05:22
	System	21 Sep 2020 16:05:22

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T12:01:14', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '894dd888-c345-4782-95ea-a281ce9125bd' User entered 'None (0)'	System	21 Sep 2020 16:05:22
	System	21 Sep 2020 16:05:22

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T12:01:16', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '894dd888-c345-4782-95ea-a281ce9125bd' User entered 'None (0)'	System	21 Sep 2020 16:05:22
	System	21 Sep 2020 16:05:22

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T12:01:18', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '894dd888-c345-4782-95ea-a281ce9125bd' User entered 'None (0)'	System	21 Sep 2020 16:05:22
	System	21 Sep 2020 16:05:22

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

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)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T12:01:25', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '894dd888-c345-4782-95ea-a281ce9125bd' User entered 'No (N)'	System	21 Sep 2020 16:05:22
	System	21 Sep 2020 16:05:22

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T12:01:28', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '894dd888-c345-4782-95ea-a281ce9125bd' User entered '21 Sep 2020 12:01'	System	21 Sep 2020 16:05:22
	System	21 Sep 2020 16:05:22

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '21 Sep 2020 11:49'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '21 Sep 2020 14:19'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	21 Sep 2020 15:33:55
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T17:44:07', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '038faded-0850-43a3-913c-ad31b2fda2b1' User entered 'None (0)'	System	21 Sep 2020 21:44:30
	System	21 Sep 2020 21:44:30

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T17:44:09', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '038faded-0850-43a3-913c-ad31b2fda2b1' User entered 'None (0)'	System	21 Sep 2020 21:44:30
	System	21 Sep 2020 21:44:30

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T17:44:11', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '038faded-0850-43a3-913c-ad31b2fda2b1' User entered 'None (0)'	System	21 Sep 2020 21:44:30
	System	21 Sep 2020 21:44:30

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T17:44:13', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '038faded-0850-43a3-913c-ad31b2fda2b1' User entered 'None (0)'	System	21 Sep 2020 21:44:30
	System	21 Sep 2020 21:44:30

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T17:44:17', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '038faded-0850-43a3-913c-ad31b2fda2b1' User entered 'None (0)'	System	21 Sep 2020 21:44:30
	System	21 Sep 2020 21:44:30

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T17:44:19', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '038faded-0850-43a3-913c-ad31b2fda2b1' User entered 'None (0)'	System	21 Sep 2020 21:44:30
	System	21 Sep 2020 21:44:30

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

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)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T17:44:26', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '038faded-0850-43a3-913c-ad31b2fda2b1' User entered 'No (N)'	System	21 Sep 2020 21:44:30
	System	21 Sep 2020 21:44:30

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-21T17:44:29', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '038faded-0850-43a3-913c-ad31b2fda2b1' User entered '21 Sep 2020 17:44'	System	21 Sep 2020 21:44:30
	System	21 Sep 2020 21:44:30

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '21 Sep 2020 15:14'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	21 Sep 2020 15:33:55
User entered 'Day 2'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-22T19:29:20', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f926fbb3-0553-4f6c-85a9-d1e72933314e' User entered 'None (0)'	System	22 Sep 2020 23:30:11
	System	22 Sep 2020 23:30:11

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-22T19:29:23', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f926fbb3-0553-4f6c-85a9-d1e72933314e' User entered 'None (0)'	System	22 Sep 2020 23:30:11
	System	22 Sep 2020 23:30:11

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-22T19:29:25', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f926fbb3-0553-4f6c-85a9-d1e72933314e' User entered 'None (0)'	System	22 Sep 2020 23:30:11
	System	22 Sep 2020 23:30:11

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-22T19:29:27', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f926fbb3-0553-4f6c-85a9-d1e72933314e' User entered 'None (0)'	System	22 Sep 2020 23:30:11
	System	22 Sep 2020 23:30:11

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-22T19:29:30', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f926fbb3-0553-4f6c-85a9-d1e72933314e' User entered 'None (0)'	System	22 Sep 2020 23:30:11
	System	22 Sep 2020 23:30:11

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-22T19:29:32', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f926fbb3-0553-4f6c-85a9-d1e72933314e' User entered 'None (0)'	System	22 Sep 2020 23:30:11
	System	22 Sep 2020 23:30:11

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:52

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)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-22T19:29:34', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f926fbb3-0553-4f6c-85a9-d1e72933314e' User entered 'No (N)'	System	22 Sep 2020 23:30:11
	System	22 Sep 2020 23:30:11

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-22T19:29:37', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f926fbb3-0553-4f6c-85a9-d1e72933314e' User entered '22 Sep 2020 19:29'	System	22 Sep 2020 23:30:11
	System	22 Sep 2020 23:30:11

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	21 Sep 2020 15:33:55
User entered 'Day 3'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-23T16:53:50', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '32a87c12-88ad-4be3-98f3-afc73437c99e' User entered 'None (0)'	System	23 Sep 2020 20:54:28
	System	23 Sep 2020 20:54:28

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-23T16:53:53', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '32a87c12-88ad-4be3-98f3-afc73437c99e' User entered 'None (0)'	System	23 Sep 2020 20:54:28
	System	23 Sep 2020 20:54:28

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-23T16:53:55', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '32a87c12-88ad-4be3-98f3-afc73437c99e' User entered 'None (0)'	System	23 Sep 2020 20:54:28
	System	23 Sep 2020 20:54:28

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-23T16:53:57', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '32a87c12-88ad-4be3-98f3-afc73437c99e' User entered 'None (0)'	System	23 Sep 2020 20:54:28
	System	23 Sep 2020 20:54:28

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-23T16:54:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '32a87c12-88ad-4be3-98f3-afc73437c99e' User entered 'None (0)'	System	23 Sep 2020 20:54:28
	System	23 Sep 2020 20:54:28

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-23T16:54:02', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '32a87c12-88ad-4be3-98f3-afc73437c99e' User entered 'None (0)'	System	23 Sep 2020 20:54:28
	System	23 Sep 2020 20:54:28

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:52

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)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-23T16:54:18', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '32a87c12-88ad-4be3-98f3-afc73437c99e' User entered 'No (N)'	System	23 Sep 2020 20:54:28
	System	23 Sep 2020 20:54:28

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-23T16:54:22', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '32a87c12-88ad-4be3-98f3-afc73437c99e' User entered '23 Sep 2020 16:54'	System	23 Sep 2020 20:54:28
	System	23 Sep 2020 20:54:28

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	21 Sep 2020 15:33:55
User entered 'Day 4'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-24T18:19:42', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '22edac0a-65d1-480f-a518-281d5ccd214b' User entered 'None (0)'	System	24 Sep 2020 22:20:04
	System	24 Sep 2020 22:20:04

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-24T18:19:44', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '22edac0a-65d1-480f-a518-281d5ccd214b' User entered 'None (0)'	System	24 Sep 2020 22:20:04
	System	24 Sep 2020 22:20:04

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-24T18:19:46', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '22edac0a-65d1-480f-a518-281d5ccd214b' User entered 'None (0)'	System	24 Sep 2020 22:20:04
	System	24 Sep 2020 22:20:04

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-24T18:19:48', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '22edac0a-65d1-480f-a518-281d5ccd214b' User entered 'None (0)'	System	24 Sep 2020 22:20:04
	System	24 Sep 2020 22:20:04

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-24T18:19:50', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '22edac0a-65d1-480f-a518-281d5ccd214b' User entered 'None (0)'	System	24 Sep 2020 22:20:04
	System	24 Sep 2020 22:20:04

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-24T18:19:53', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '22edac0a-65d1-480f-a518-281d5ccd214b' User entered 'None (0)'	System	24 Sep 2020 22:20:04
	System	24 Sep 2020 22:20:04

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:52

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)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-24T18:19:57', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '22edac0a-65d1-480f-a518-281d5ccd214b' User entered 'No (N)'	System	24 Sep 2020 22:20:04
	System	24 Sep 2020 22:20:04

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-24T18:20:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '22edac0a-65d1-480f-a518-281d5ccd214b' User entered '24 Sep 2020 18:20'	System	24 Sep 2020 22:20:04
	System	24 Sep 2020 22:20:04

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	21 Sep 2020 15:33:55
User entered 'Day 5'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T00:30:32', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f3706180-2ed1-4ed1-b578-10ad2081bb20' User entered 'None (0)'	System	26 Sep 2020 04:31:03
	System	26 Sep 2020 04:31:03

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T00:30:37', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f3706180-2ed1-4ed1-b578-10ad2081bb20' User entered 'None (0)'	System	26 Sep 2020 04:31:03
	System	26 Sep 2020 04:31:03

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T00:30:47', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f3706180-2ed1-4ed1-b578-10ad2081bb20'	System	26 Sep 2020 04:31:03
User entered 'No interference with activity (1)'	System	26 Sep 2020 04:31:03

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T00:30:50', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f3706180-2ed1-4ed1-b578-10ad2081bb20'	System	26 Sep 2020 04:31:03
User entered 'No interference with activity (1)'	System	26 Sep 2020 04:31:03

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T00:30:52', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f3706180-2ed1-4ed1-b578-10ad2081bb20' User entered 'None (0)'	System	26 Sep 2020 04:31:03
	System	26 Sep 2020 04:31:03

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T00:30:54', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f3706180-2ed1-4ed1-b578-10ad2081bb20' User entered 'None (0)'	System	26 Sep 2020 04:31:03
	System	26 Sep 2020 04:31:03

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:52

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)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T00:30:57', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f3706180-2ed1-4ed1-b578-10ad2081bb20' User entered 'No (N)'	System	26 Sep 2020 04:31:03
	System	26 Sep 2020 04:31:03

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T00:30:59', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f3706180-2ed1-4ed1-b578-10ad2081bb20' User entered '26 Sep 2020 00:30'	System	26 Sep 2020 04:31:03
	System	26 Sep 2020 04:31:03

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	21 Sep 2020 15:33:55
User entered 'Day 6'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T16:38:24', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '9744b102-2185-493b-90c6-13b2a58eb5f6' User entered 'None (0)'	System	26 Sep 2020 20:38:51
	System	26 Sep 2020 20:38:51

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T16:38:27', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '9744b102-2185-493b-90c6-13b2a58eb5f6' User entered 'None (0)'	System	26 Sep 2020 20:38:51
	System	26 Sep 2020 20:38:51

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T16:38:35', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '9744b102-2185-493b-90c6-13b2a58eb5f6' User entered 'None (0)'	System	26 Sep 2020 20:38:51
	System	26 Sep 2020 20:38:51

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T16:38:39', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '9744b102-2185-493b-90c6-13b2a58eb5f6'	System	26 Sep 2020 20:38:51
User entered 'No interference with activity (1)'	System	26 Sep 2020 20:38:51

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T16:38:41', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '9744b102-2185-493b-90c6-13b2a58eb5f6' User entered 'None (0)'	System	26 Sep 2020 20:38:51
	System	26 Sep 2020 20:38:51

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T16:38:43', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '9744b102-2185-493b-90c6-13b2a58eb5f6' User entered 'None (0)'	System	26 Sep 2020 20:38:51
	System	26 Sep 2020 20:38:51

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:52

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)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T16:38:46', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '9744b102-2185-493b-90c6-13b2a58eb5f6' User entered 'No (N)'	System	26 Sep 2020 20:38:51
	System	26 Sep 2020 20:38:51

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-26T16:38:50', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '9744b102-2185-493b-90c6-13b2a58eb5f6' User entered '26 Sep 2020 16:38'	System	26 Sep 2020 20:38:51
	System	26 Sep 2020 20:38:51

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	21 Sep 2020 15:33:55
User entered 'Day 7'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-28T05:47:41', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '15b06404-f17b-4813-b0ab-762983989ca6' User entered 'None (0)'	System	28 Sep 2020 09:48:05
	System	28 Sep 2020 09:48:05

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-28T05:47:43', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '15b06404-f17b-4813-b0ab-762983989ca6' User entered 'None (0)'	System	28 Sep 2020 09:48:05
	System	28 Sep 2020 09:48:05

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-28T05:47:48', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '15b06404-f17b-4813-b0ab-762983989ca6' User entered 'None (0)'	System	28 Sep 2020 09:48:05
	System	28 Sep 2020 09:48:05

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-28T05:47:53', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '15b06404-f17b-4813-b0ab-762983989ca6'	System	28 Sep 2020 09:48:05
User entered 'No interference with activity (1)'	System	28 Sep 2020 09:48:05

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-28T05:47:56', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '15b06404-f17b-4813-b0ab-762983989ca6' User entered 'None (0)'	System	28 Sep 2020 09:48:05
	System	28 Sep 2020 09:48:05

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-28T05:47:58', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '15b06404-f17b-4813-b0ab-762983989ca6' User entered 'None (0)'	System	28 Sep 2020 09:48:05
	System	28 Sep 2020 09:48:05

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:52

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)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-28T05:48:01', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '15b06404-f17b-4813-b0ab-762983989ca6' User entered 'No (N)'	System	28 Sep 2020 09:48:05
	System	28 Sep 2020 09:48:05

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-28T05:48:03', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '15b06404-f17b-4813-b0ab-762983989ca6' User entered '28 Sep 2020 05:48'	System	28 Sep 2020 09:48:05
	System	28 Sep 2020 09:48:05

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 15:33:55

US3702040

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	26 Sep 2020 20:38:51
User entered 'Day 8'	System	26 Sep 2020 20:38:51

US3702040

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:18:52

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-28T20:20:48', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f818718e-209b-490f-b17c-294b8376c7d5'	System	29 Sep 2020 00:20:56
User entered 'No interference with activity (1)'	System	29 Sep 2020 00:20:56

US3702040

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:18:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-28T20:20:51', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f818718e-209b-490f-b17c-294b8376c7d5' User entered '28 Sep 2020 20:20'	System	29 Sep 2020 00:20:56
	System	29 Sep 2020 00:20:56

US3702040

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 20:38:51

US3702040

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 20:38:51

US3702040

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	28 Sep 2020 09:48:05
User entered 'Day 9'	System	28 Sep 2020 09:48:05

US3702040

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:18:52

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-30T07:33:22', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '64438348-5284-48fc-9b97-6b317b8303ef' User entered 'None (0)'	System	30 Sep 2020 11:33:50
	System	30 Sep 2020 11:33:50

US3702040

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:18:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-30T07:33:25', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '64438348-5284-48fc-9b97-6b317b8303ef' User entered '30 Sep 2020 07:33'	System	30 Sep 2020 11:33:50
	System	30 Sep 2020 11:33:50

US3702040

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 09:48:05

US3702040

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 09:48:05

US3702040

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	26 Sep 2020 20:38:51
User entered 'Day 8'	System	26 Sep 2020 20:38:51

US3702040

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:18:52

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)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-28T20:20:55', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '1ab7d089-f15f-43f9-ad4a-b90830df243e' User entered 'No (N)'	System	29 Sep 2020 00:21:05
	System	29 Sep 2020 00:21:05

US3702040

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:18:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-28T20:20:59', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '1ab7d089-f15f-43f9-ad4a-b90830df243e' User entered '28 Sep 2020 20:20'	System	29 Sep 2020 00:21:05
	System	29 Sep 2020 00:21:05

US3702040

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 20:38:51

US3702040

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 20:38:51

US3702040

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	28 Sep 2020 09:48:05
User entered 'Day 9'	System	28 Sep 2020 09:48:05

US3702040

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:18:52

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)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-30T07:33:28', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'cae36abc-940d-4f97-a00f-88df0fbc52e7' User entered 'No (N)'	System	30 Sep 2020 11:33:59
	System	30 Sep 2020 11:33:59

US3702040

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:18:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-09-30T07:33:30', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'cae36abc-940d-4f97-a00f-88df0fbc52e7' User entered '30 Sep 2020 07:33'	System	30 Sep 2020 11:33:59
	System	30 Sep 2020 11:33:59

US3702040

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 09:48:05

US3702040

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 09:48:05

US3702040

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Oct 2020 21:21:46

US3702040

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '28 Sep 2020'	Jiamin Li (b) (4)	12 Oct 2020 21:21:46

US3702040

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	12 Oct 2020 21:21:46

US3702040

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 21:21:46

US3702040

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Oct 2020 21:22:06

US3702040

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User entered 'I'	System	12 Oct 2020 21:22:06

US3702040

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Oct 2020 21:25:44

US3702040

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '07 Oct 2020'	Jiamin Li (b) (4)	12 Oct 2020 21:25:44

US3702040

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	12 Oct 2020 21:25:44

US3702040

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 21:25:44

US3702040

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Oct 2020 21:25:50

US3702040

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:17
User entered 'I'	System	12 Oct 2020 21:25:50

US3702040

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Genessi Rodriguez (b) (4)	19 Oct 2020 14:33:18

US3702040

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '14 Oct 2020'	Genessi Rodriguez (b) (4)	19 Oct 2020 14:33:18

US3702040

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Contact Made (CONTACT MADE)'	Genessi Rodriguez (b) (4)	19 Oct 2020 14:33:18

US3702040

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Genessi Rodriguez (b) (4)	19 Oct 2020 14:33:18

US3702040

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Genessi Rodriguez (b) (4)	19 Oct 2020 14:33:26

US3702040

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered 'I'	System	19 Oct 2020 14:33:26

US3702040

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Caique Mello (b) (4)	20 Oct 2020 14:09:46

US3702040

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '20 Oct 2020'	Caique Mello (b) (4)	20 Oct 2020 14:09:46

US3702040

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Clinic (Clinic)'	Caique Mello (b) (4)	20 Oct 2020 14:09:46

US3702040

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered 'VISIT2'	System	20 Oct 2020 14:09:46

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User accepted default value 'Pre-Dose (PREDOSE)'	Jiamin Li (b) (4) (b) (4)	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '20 Oct 2020'	Jiamin Li (b) (4)	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '09:35'	Jiamin Li (b) (4)	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered '20 Oct 2020 09:35'	System	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '37.1' C	Jiamin Li (b) (4)	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Oral (Oral)'	Jiamin Li (b) (4)	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '73'	Jiamin Li (b) (4)	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered 'bpm'	System	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '16'	Jiamin Li (b) (4)	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered 'breaths/min'	System	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '118'	Jiamin Li (b) (4)	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered 'mmHg'	System	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '76'	Jiamin Li (b) (4)	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered 'mmHg'	System	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User accepted default value 'Post-Dose (POSTDOSE)'	Jiamin Li (b) (4) (b) (4)	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '20 Oct 2020'	Jiamin Li (b) (4)	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '10:39'	Jiamin Li (b) (4)	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered '20 Oct 2020 10:39'	System	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '36.9' C	Jiamin Li (b) (4)	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Oral (Oral)'	Jiamin Li (b) (4)	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '61'	Jiamin Li (b) (4)	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered 'bpm'	System	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '16'	Jiamin Li (b) (4)	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered 'breaths/min'	System	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '123'	Jiamin Li (b) (4)	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered 'mmHg'	System	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '82'	Jiamin Li (b) (4)	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered 'mmHg'	System	26 Oct 2020 18:22:56

US3702040

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	26 Oct 2020 18:21:18

US3702040

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '20 Oct 2020'	Jiamin Li (b) (4)	26 Oct 2020 18:21:18

US3702040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Caique Mello (b) (4)	20 Oct 2020 14:10:15

US3702040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Caique Mello (b) (4)	20 Oct 2020 14:10:15

US3702040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Caique Mello (b) (4)	20 Oct 2020 14:10:15

US3702040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered 'MRNA-1273 OR PLACEBO'	System	20 Oct 2020 14:10:15

US3702040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '20 Oct 2020'	Caique Mello (b) (4)	20 Oct 2020 14:10:15

US3702040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '10:05'	Caique Mello (b) (4)	20 Oct 2020 14:10:15

US3702040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered '20 Oct 2020 10:05'	System	20 Oct 2020 14:10:15

US3702040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Left Arm (LEFT ARM)'	Caique Mello (b) (4)	20 Oct 2020 14:10:15

US3702040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered 'ONCE'	System	20 Oct 2020 14:10:15

US3702040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered 'INTRAMUSCULAR'	System	20 Oct 2020 14:10:15

US3702040

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	26 Oct 2020 18:23:50

US3702040

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '20 Oct 2020'	Jiamin Li (b) (4)	26 Oct 2020 18:23:50

US3702040

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:52

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '09:55'	Jiamin Li (b) (4)	26 Oct 2020 18:23:50

US3702040

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered '20 Oct 2020 09:55'	System	26 Oct 2020 18:23:50

US3702040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:18:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '20 Oct 2020'	Jiamin Li (b) (4)	26 Oct 2020 18:23:21

US3702040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:18:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jiamin Li (b) (4) (b) (4)	26 Oct 2020 18:23:21

US3702040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:18:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	26 Oct 2020 18:23:21

US3702040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:18:52

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '10:02'	Jiamin Li (b) (4)	26 Oct 2020 18:23:21

US3702040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered '20 Oct 2020 10:02'	System	26 Oct 2020 18:23:21

US3702040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:18:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jiamin Li (b) (4) (b) (4)	26 Oct 2020 18:23:21

US3702040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:18:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	26 Oct 2020 18:23:21

US3702040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:18:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	26 Oct 2020 18:23:21

US3702040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered empty.	System	26 Oct 2020 18:23:21

US3702040

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	26 Oct 2020 18:23:26

US3702040

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered 'I'	System	26 Oct 2020 18:23:26

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	20 Oct 2020 14:10:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T10:37:12', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'a830fb10-aca5-43f3-a80e-61d7e7992616' User entered 'Yes (Y)'	System	20 Oct 2020 14:40:46
	System	20 Oct 2020 14:40:46

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T10:40:19', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'a830fb10-aca5-43f3-a80e-61d7e7992616' User entered '98.8'	System	20 Oct 2020 14:40:46
	System	20 Oct 2020 14:40:46

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T10:40:22', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'a830fb10-aca5-43f3-a80e-61d7e7992616' User entered 'No (N)'	System	20 Oct 2020 14:40:46
	System	20 Oct 2020 14:40:46

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T10:40:43', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'a830fb10-aca5-43f3-a80e-61d7e7992616' User entered '20 Oct 2020 10:40'	System	20 Oct 2020 14:40:46
	System	20 Oct 2020 14:40:46

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '20 Oct 2020 10:25'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '20 Oct 2020 12:55'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	20 Oct 2020 14:10:15
User entered 'Day 1, after vaccination (at home)'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T20:34:38', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '4d260a9d-4562-4bdc-b8b0-447d2e4be5a1' User entered 'Yes (Y)'	System	21 Oct 2020 00:35:04
	System	21 Oct 2020 00:35:04

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T20:34:43', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '4d260a9d-4562-4bdc-b8b0-447d2e4be5a1' User entered '98.7'	System	21 Oct 2020 00:35:04
	System	21 Oct 2020 00:35:04

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T20:34:46', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '4d260a9d-4562-4bdc-b8b0-447d2e4be5a1'	System	21 Oct 2020 00:35:04
User entered 'No (N)'	System	21 Oct 2020 00:35:04

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T20:34:50', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '4d260a9d-4562-4bdc-b8b0-447d2e4be5a1' User entered '20 Oct 2020 20:34'	System	21 Oct 2020 00:35:04
	System	21 Oct 2020 00:35:04

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '20 Oct 2020 13:50'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	20 Oct 2020 14:10:15
User entered 'Day 2'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-21T18:17:50', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '39893336-dcdb-4710-896c-77bbd7480944' User entered 'Yes (Y)'	System	21 Oct 2020 22:18:06
	System	21 Oct 2020 22:18:06

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-21T18:17:55', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '39893336-dcdb-4710-896c-77bbd7480944' User entered '98.8'	System	21 Oct 2020 22:18:06
	System	21 Oct 2020 22:18:06

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-21T18:17:57', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '39893336-dcdb-4710-896c-77bbd7480944'	System	21 Oct 2020 22:18:06
User entered 'No (N)'	System	21 Oct 2020 22:18:06

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-21T18:18:01', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '39893336-dcdb-4710-896c-77bbd7480944' User entered '21 Oct 2020 18:18'	System	21 Oct 2020 22:18:06
	System	21 Oct 2020 22:18:06

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	20 Oct 2020 14:10:15
User entered 'Day 3'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-22T17:30:24', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'fa193a90-7647-4304-9b8c-01b3b8bb373b' User entered 'Yes (Y)'	System	22 Oct 2020 21:30:39
	System	22 Oct 2020 21:30:39

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-22T17:30:27', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'fa193a90-7647-4304-9b8c-01b3b8bb373b' User entered '98.5'	System	22 Oct 2020 21:30:39
	System	22 Oct 2020 21:30:39

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-22T17:30:30', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'fa193a90-7647-4304-9b8c-01b3b8bb373b' User entered 'No (N)'	System	22 Oct 2020 21:30:39
	System	22 Oct 2020 21:30:39

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-22T17:30:34', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'fa193a90-7647-4304-9b8c-01b3b8bb373b' User entered '22 Oct 2020 17:30'	System	22 Oct 2020 21:30:39
	System	22 Oct 2020 21:30:39

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	20 Oct 2020 14:10:15
User entered 'Day 4'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-23T20:33:26', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '02b60c04-fdea-4f26-897b-a02ebf1ce3f3' User entered 'Yes (Y)'	System	24 Oct 2020 00:33:40
	System	24 Oct 2020 00:33:40

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-23T20:33:32', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '02b60c04-fdea-4f26-897b-a02ebf1ce3f3' User entered '98.0'	System	24 Oct 2020 00:33:40
	System	24 Oct 2020 00:33:40

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-23T20:33:34', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '02b60c04-fdea-4f26-897b-a02ebf1ce3f3'	System	24 Oct 2020 00:33:40
User entered 'No (N)'	System	24 Oct 2020 00:33:40

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-23T20:33:37', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '02b60c04-fdea-4f26-897b-a02ebf1ce3f3'	System	24 Oct 2020 00:33:40
User entered '23 Oct 2020 20:33'	System	24 Oct 2020 00:33:40

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '23 Oct 2020 12:00'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '24 Oct 2020 11:59'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	20 Oct 2020 14:10:15
User entered 'Day 5'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-24T15:58:05', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'ea3a1ca9-89c2-4f72-a28f-90151077b4f3' User entered 'Yes (Y)'	System	24 Oct 2020 19:58:30
	System	24 Oct 2020 19:58:30

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-24T15:58:11', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'ea3a1ca9-89c2-4f72-a28f-90151077b4f3' User entered '98.8'	System	24 Oct 2020 19:58:30
	System	24 Oct 2020 19:58:30

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-24T15:58:23', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'ea3a1ca9-89c2-4f72-a28f-90151077b4f3' User entered 'No (N)'	System	24 Oct 2020 19:58:30
	System	24 Oct 2020 19:58:30

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-24T15:58:26', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'ea3a1ca9-89c2-4f72-a28f-90151077b4f3' User entered '24 Oct 2020 15:58'	System	24 Oct 2020 19:58:30
	System	24 Oct 2020 19:58:30

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '24 Oct 2020 12:00'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '25 Oct 2020 11:59'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	20 Oct 2020 14:10:15
User entered 'Day 6'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T00:34:12', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'dcb1a5f1-73b0-4ca3-9681-ab40e0a1363b' User entered 'Yes (Y)'	System	26 Oct 2020 04:34:24
	System	26 Oct 2020 04:34:24

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T00:34:16', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'dcb1a5f1-73b0-4ca3-9681-ab40e0a1363b' User entered '98.6'	System	26 Oct 2020 04:34:24
	System	26 Oct 2020 04:34:24

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T00:34:19', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'dcb1a5f1-73b0-4ca3-9681-ab40e0a1363b' User entered 'No (N)'	System	26 Oct 2020 04:34:24
	System	26 Oct 2020 04:34:24

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T00:34:22', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'dcb1a5f1-73b0-4ca3-9681-ab40e0a1363b' User entered '26 Oct 2020 00:34'	System	26 Oct 2020 04:34:24
	System	26 Oct 2020 04:34:24

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '25 Oct 2020 12:00'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '26 Oct 2020 11:59'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	20 Oct 2020 14:10:15
User entered 'Day 7'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T19:00:02', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '5cc66e08-20db-412e-a3f3-f6c5a23b0ee6' User entered 'Yes (Y)'	System	26 Oct 2020 23:01:37
	System	26 Oct 2020 23:01:37

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T19:00:08', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '5cc66e08-20db-412e-a3f3-f6c5a23b0ee6' User entered '99.0'	System	26 Oct 2020 23:01:37
	System	26 Oct 2020 23:01:37

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T19:01:29', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '5cc66e08-20db-412e-a3f3-f6c5a23b0ee6'	System	26 Oct 2020 23:01:37
User entered 'No (N)'	System	26 Oct 2020 23:01:37

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T19:01:31', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '5cc66e08-20db-412e-a3f3-f6c5a23b0ee6' User entered '26 Oct 2020 19:01'	System	26 Oct 2020 23:01:37
	System	26 Oct 2020 23:01:37

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '26 Oct 2020 12:00'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '27 Oct 2020 11:59'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	20 Oct 2020 14:10:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T10:40:47', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '4e7719f1-e983-4af6-ae02-36c837b34316'	System	20 Oct 2020 14:41:04
User entered 'None (1)'	System	20 Oct 2020 14:41:04

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T10:40:50', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '4e7719f1-e983-4af6-ae02-36c837b34316' User entered 'No (N)'	System	20 Oct 2020 14:41:04
	System	20 Oct 2020 14:41:04

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T10:40:53', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '4e7719f1-e983-4af6-ae02-36c837b34316'	System	20 Oct 2020 14:41:04
User entered 'No (N)'	System	20 Oct 2020 14:41:04

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T10:40:55', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '4e7719f1-e983-4af6-ae02-36c837b34316'	System	20 Oct 2020 14:41:04
User entered 'None (1)'	System	20 Oct 2020 14:41:04

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T10:41:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '4e7719f1-e983-4af6-ae02-36c837b34316' User entered '20 Oct 2020 10:41'	System	20 Oct 2020 14:41:04
	System	20 Oct 2020 14:41:04

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '20 Oct 2020 10:25'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '20 Oct 2020 12:55'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	20 Oct 2020 14:10:15
User entered 'Day 1, after vaccination (at home)'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T20:34:53', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '663503e1-95b6-465e-aa92-e958c0a0739c' User entered 'None (1)'	System	21 Oct 2020 00:35:11
	System	21 Oct 2020 00:35:11

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T20:34:57', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '663503e1-95b6-465e-aa92-e958c0a0739c' User entered 'No (N)'	System	21 Oct 2020 00:35:11
	System	21 Oct 2020 00:35:11

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T20:34:59', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '663503e1-95b6-465e-aa92-e958c0a0739c' User entered 'No (N)'	System	21 Oct 2020 00:35:11
	System	21 Oct 2020 00:35:11

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T20:35:02', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '663503e1-95b6-465e-aa92-e958c0a0739c' User entered 'None (1)'	System	21 Oct 2020 00:35:11
	System	21 Oct 2020 00:35:11

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T20:35:07', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '663503e1-95b6-465e-aa92-e958c0a0739c' User entered '20 Oct 2020 20:35'	System	21 Oct 2020 00:35:11
	System	21 Oct 2020 00:35:11

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '20 Oct 2020 13:50'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	20 Oct 2020 14:10:15
User entered 'Day 2'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-21T18:18:05', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f4eeadba-b292-4237-8422-617a79790762'	System	21 Oct 2020 22:18:48
User entered 'None (1)'	System	21 Oct 2020 22:18:48

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-21T18:18:07', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f4eeadba-b292-4237-8422-617a79790762' User entered 'No (N)'	System	21 Oct 2020 22:18:48
	System	21 Oct 2020 22:18:48

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-21T18:18:09', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f4eeadba-b292-4237-8422-617a79790762'	System	21 Oct 2020 22:18:48
User entered 'No (N)'	System	21 Oct 2020 22:18:48

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-21T18:18:11', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f4eeadba-b292-4237-8422-617a79790762'	System	21 Oct 2020 22:18:48
User entered 'None (1)'	System	21 Oct 2020 22:18:48

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-21T18:18:45', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f4eeadba-b292-4237-8422-617a79790762' User entered '21 Oct 2020 18:18'	System	21 Oct 2020 22:18:48
	System	21 Oct 2020 22:18:48

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	20 Oct 2020 14:10:15
User entered 'Day 3'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-22T17:30:41', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '4bd26ede-9c38-41eb-9a46-ae6d29770ed7'	System	22 Oct 2020 21:30:53
User entered 'None (1)'	System	22 Oct 2020 21:30:53

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-22T17:30:43', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '4bd26ede-9c38-41eb-9a46-ae6d29770ed7'	System	22 Oct 2020 21:30:53
User entered 'No (N)'	System	22 Oct 2020 21:30:53

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-22T17:30:44', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '4bd26ede-9c38-41eb-9a46-ae6d29770ed7'	System	22 Oct 2020 21:30:53
User entered 'No (N)'	System	22 Oct 2020 21:30:53

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-22T17:30:46', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '4bd26ede-9c38-41eb-9a46-ae6d29770ed7'	System	22 Oct 2020 21:30:53
User entered 'None (1)'	System	22 Oct 2020 21:30:53

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-22T17:30:49', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '4bd26ede-9c38-41eb-9a46-ae6d29770ed7' User entered '22 Oct 2020 17:30'	System	22 Oct 2020 21:30:53
	System	22 Oct 2020 21:30:53

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	20 Oct 2020 14:10:15
User entered 'Day 4'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-23T20:33:46', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'b0f82aad-7976-4f75-bdb3-16ed275ee6ad' User entered 'None (1)'	System	24 Oct 2020 00:34:09
	System	24 Oct 2020 00:34:09

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-23T20:33:49', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'b0f82aad-7976-4f75-bdb3-16ed275ee6ad' User entered 'No (N)'	System	24 Oct 2020 00:34:09
	System	24 Oct 2020 00:34:09

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-23T20:33:52', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'b0f82aad-7976-4f75-bdb3-16ed275ee6ad' User entered 'No (N)'	System	24 Oct 2020 00:34:09
	System	24 Oct 2020 00:34:09

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-23T20:33:54', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'b0f82aad-7976-4f75-bdb3-16ed275ee6ad' User entered 'None (1)'	System	24 Oct 2020 00:34:09
	System	24 Oct 2020 00:34:09

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-23T20:34:02', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'b0f82aad-7976-4f75-bdb3-16ed275ee6ad' User entered '23 Oct 2020 20:34'	System	24 Oct 2020 00:34:09
	System	24 Oct 2020 00:34:09

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '23 Oct 2020 12:00'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '24 Oct 2020 11:59'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	20 Oct 2020 14:10:15
User entered 'Day 5'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-24T15:58:30', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'be922710-d3b9-47d4-8f0c-b0f874272165' User entered 'None (1)'	System	24 Oct 2020 19:58:40
	System	24 Oct 2020 19:58:40

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-24T15:58:31', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'be922710-d3b9-47d4-8f0c-b0f874272165' User entered 'No (N)'	System	24 Oct 2020 19:58:40
	System	24 Oct 2020 19:58:40

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-24T15:58:33', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'be922710-d3b9-47d4-8f0c-b0f874272165' User entered 'No (N)'	System	24 Oct 2020 19:58:40
	System	24 Oct 2020 19:58:40

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-24T15:58:35', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'be922710-d3b9-47d4-8f0c-b0f874272165'	System	24 Oct 2020 19:58:40
User entered 'None (1)'	System	24 Oct 2020 19:58:40

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-24T15:58:38', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'be922710-d3b9-47d4-8f0c-b0f874272165' User entered '24 Oct 2020 15:58'	System	24 Oct 2020 19:58:40
	System	24 Oct 2020 19:58:40

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '24 Oct 2020 12:00'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '25 Oct 2020 11:59'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	20 Oct 2020 14:10:15
User entered 'Day 6'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T00:34:26', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '44165939-9813-4580-b190-bfc55b81ccc9' User entered 'None (1)'	System	26 Oct 2020 04:34:37
	System	26 Oct 2020 04:34:37

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T00:34:28', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '44165939-9813-4580-b190-bfc55b81ccc9' User entered 'No (N)'	System	26 Oct 2020 04:34:37
	System	26 Oct 2020 04:34:37

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T00:34:29', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '44165939-9813-4580-b190-bfc55b81ccc9' User entered 'No (N)'	System	26 Oct 2020 04:34:37
	System	26 Oct 2020 04:34:37

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T00:34:31', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '44165939-9813-4580-b190-bfc55b81ccc9' User entered 'None (1)'	System	26 Oct 2020 04:34:37
	System	26 Oct 2020 04:34:37

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T00:34:33', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '44165939-9813-4580-b190-bfc55b81ccc9' User entered '26 Oct 2020 00:34'	System	26 Oct 2020 04:34:37
	System	26 Oct 2020 04:34:37

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '25 Oct 2020 12:00'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '26 Oct 2020 11:59'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	20 Oct 2020 14:10:15
User entered 'Day 7'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T19:01:35', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '8a3c93f3-cdfe-41ac-8ff0-419b8eeb3715'	System	26 Oct 2020 23:01:48
User entered 'None (1)'	System	26 Oct 2020 23:01:48

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T19:01:37', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '8a3c93f3-cdfe-41ac-8ff0-419b8eeb3715'	System	26 Oct 2020 23:01:48
User entered 'No (N)'	System	26 Oct 2020 23:01:48

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T19:01:39', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '8a3c93f3-cdfe-41ac-8ff0-419b8eeb3715' User entered 'No (N)'	System	26 Oct 2020 23:01:48
	System	26 Oct 2020 23:01:48

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T19:01:41', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '8a3c93f3-cdfe-41ac-8ff0-419b8eeb3715'	System	26 Oct 2020 23:01:48
User entered 'None (1)'	System	26 Oct 2020 23:01:48

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T19:01:43', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '8a3c93f3-cdfe-41ac-8ff0-419b8eeb3715' User entered '26 Oct 2020 19:01'	System	26 Oct 2020 23:01:48
	System	26 Oct 2020 23:01:48

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '26 Oct 2020 12:00'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '27 Oct 2020 11:59'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	20 Oct 2020 14:10:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T10:41:04', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'bdd5f3af-42d2-4b58-8aba-a9691a2cf785' User entered 'None (0)'	System	20 Oct 2020 14:41:25
	System	20 Oct 2020 14:41:25

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T10:41:06', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'bdd5f3af-42d2-4b58-8aba-a9691a2cf785' User entered 'None (0)'	System	20 Oct 2020 14:41:25
	System	20 Oct 2020 14:41:25

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T10:41:08', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'bdd5f3af-42d2-4b58-8aba-a9691a2cf785' User entered 'None (0)'	System	20 Oct 2020 14:41:25
	System	20 Oct 2020 14:41:25

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T10:41:10', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'bdd5f3af-42d2-4b58-8aba-a9691a2cf785' User entered 'None (0)'	System	20 Oct 2020 14:41:25
	System	20 Oct 2020 14:41:25

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T10:41:12', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'bdd5f3af-42d2-4b58-8aba-a9691a2cf785' User entered 'None (0)'	System	20 Oct 2020 14:41:25
	System	20 Oct 2020 14:41:25

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T10:41:14', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'bdd5f3af-42d2-4b58-8aba-a9691a2cf785' User entered 'None (0)'	System	20 Oct 2020 14:41:25
	System	20 Oct 2020 14:41:25

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

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)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T10:41:18', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'bdd5f3af-42d2-4b58-8aba-a9691a2cf785'	System	20 Oct 2020 14:41:25
User entered 'No (N)'	System	20 Oct 2020 14:41:25

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T10:41:21', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'bdd5f3af-42d2-4b58-8aba-a9691a2cf785'	System	20 Oct 2020 14:41:25
User entered '20 Oct 2020 10:41'	System	20 Oct 2020 14:41:25

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '20 Oct 2020 10:25'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '20 Oct 2020 12:55'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	20 Oct 2020 14:10:15
User entered 'Day 1, after vaccination (at home)'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T20:35:11', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f5f68d6b-deab-4717-a1d6-0dbe09937bc6' User entered 'None (0)'	System	21 Oct 2020 00:35:29
	System	21 Oct 2020 00:35:29

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T20:35:13', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f5f68d6b-deab-4717-a1d6-0dbe09937bc6' User entered 'None (0)'	System	21 Oct 2020 00:35:29
	System	21 Oct 2020 00:35:29

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T20:35:15', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f5f68d6b-deab-4717-a1d6-0dbe09937bc6' User entered 'None (0)'	System	21 Oct 2020 00:35:29
	System	21 Oct 2020 00:35:29

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T20:35:16', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f5f68d6b-deab-4717-a1d6-0dbe09937bc6' User entered 'None (0)'	System	21 Oct 2020 00:35:29
	System	21 Oct 2020 00:35:29

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T20:35:19', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f5f68d6b-deab-4717-a1d6-0dbe09937bc6' User entered 'None (0)'	System	21 Oct 2020 00:35:29
	System	21 Oct 2020 00:35:29

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T20:35:21', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f5f68d6b-deab-4717-a1d6-0dbe09937bc6' User entered 'None (0)'	System	21 Oct 2020 00:35:29
	System	21 Oct 2020 00:35:29

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

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)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T20:35:24', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f5f68d6b-deab-4717-a1d6-0dbe09937bc6' User entered 'No (N)'	System	21 Oct 2020 00:35:29
	System	21 Oct 2020 00:35:29

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-20T20:35:27', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f5f68d6b-deab-4717-a1d6-0dbe09937bc6' User entered '20 Oct 2020 20:35'	System	21 Oct 2020 00:35:29
	System	21 Oct 2020 00:35:29

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '20 Oct 2020 13:50'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	20 Oct 2020 14:10:15
User entered 'Day 2'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-21T18:31:15', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '18211351-3378-4b70-8004-ae9f3ab402a5' User entered 'None (0)'	System	21 Oct 2020 22:31:30
	System	21 Oct 2020 22:31:30

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-21T18:31:16', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '18211351-3378-4b70-8004-ae9f3ab402a5' User entered 'None (0)'	System	21 Oct 2020 22:31:30
	System	21 Oct 2020 22:31:30

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-21T18:31:18', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '18211351-3378-4b70-8004-ae9f3ab402a5' User entered 'None (0)'	System	21 Oct 2020 22:31:30
	System	21 Oct 2020 22:31:30

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-21T18:31:19', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '18211351-3378-4b70-8004-ae9f3ab402a5' User entered 'None (0)'	System	21 Oct 2020 22:31:30
	System	21 Oct 2020 22:31:30

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-21T18:31:21', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '18211351-3378-4b70-8004-ae9f3ab402a5' User entered 'None (0)'	System	21 Oct 2020 22:31:30
	System	21 Oct 2020 22:31:30

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-21T18:31:22', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '18211351-3378-4b70-8004-ae9f3ab402a5' User entered 'None (0)'	System	21 Oct 2020 22:31:30
	System	21 Oct 2020 22:31:30

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:52

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)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-21T18:31:25', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '18211351-3378-4b70-8004-ae9f3ab402a5' User entered 'No (N)'	System	21 Oct 2020 22:31:30
	System	21 Oct 2020 22:31:30

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-21T18:31:29', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '18211351-3378-4b70-8004-ae9f3ab402a5' User entered '21 Oct 2020 18:31'	System	21 Oct 2020 22:31:30
	System	21 Oct 2020 22:31:30

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	20 Oct 2020 14:10:15
User entered 'Day 3'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-22T17:30:52', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '6372c257-8084-4aae-a991-44d746e115da' User entered 'None (0)'	System	22 Oct 2020 21:31:07
	System	22 Oct 2020 21:31:07

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-22T17:30:54', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '6372c257-8084-4aae-a991-44d746e115da' User entered 'None (0)'	System	22 Oct 2020 21:31:07
	System	22 Oct 2020 21:31:07

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-22T17:30:55', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '6372c257-8084-4aae-a991-44d746e115da' User entered 'None (0)'	System	22 Oct 2020 21:31:07
	System	22 Oct 2020 21:31:07

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-22T17:30:57', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '6372c257-8084-4aae-a991-44d746e115da' User entered 'None (0)'	System	22 Oct 2020 21:31:07
	System	22 Oct 2020 21:31:07

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-22T17:30:58', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '6372c257-8084-4aae-a991-44d746e115da' User entered 'None (0)'	System	22 Oct 2020 21:31:07
	System	22 Oct 2020 21:31:07

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-22T17:31:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '6372c257-8084-4aae-a991-44d746e115da' User entered 'None (0)'	System	22 Oct 2020 21:31:07
	System	22 Oct 2020 21:31:07

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:52

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)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-22T17:31:02', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '6372c257-8084-4aae-a991-44d746e115da' User entered 'No (N)'	System	22 Oct 2020 21:31:07
	System	22 Oct 2020 21:31:07

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-22T17:31:05', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '6372c257-8084-4aae-a991-44d746e115da' User entered '22 Oct 2020 17:31'	System	22 Oct 2020 21:31:07
	System	22 Oct 2020 21:31:07

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	20 Oct 2020 14:10:15
User entered 'Day 4'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-23T20:34:10', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'bc20f34f-e390-4be1-92f1-61a57164cdf6' User entered 'None (0)'	System	24 Oct 2020 00:34:27
	System	24 Oct 2020 00:34:27

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-23T20:34:11', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'bc20f34f-e390-4be1-92f1-61a57164cdf6' User entered 'None (0)'	System	24 Oct 2020 00:34:27
	System	24 Oct 2020 00:34:27

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-23T20:34:13', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'bc20f34f-e390-4be1-92f1-61a57164cdf6' User entered 'None (0)'	System	24 Oct 2020 00:34:27
	System	24 Oct 2020 00:34:27

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-23T20:34:14', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'bc20f34f-e390-4be1-92f1-61a57164cdf6' User entered 'None (0)'	System	24 Oct 2020 00:34:27
	System	24 Oct 2020 00:34:27

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-23T20:34:16', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'bc20f34f-e390-4be1-92f1-61a57164cdf6' User entered 'None (0)'	System	24 Oct 2020 00:34:27
	System	24 Oct 2020 00:34:27

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-23T20:34:18', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'bc20f34f-e390-4be1-92f1-61a57164cdf6' User entered 'None (0)'	System	24 Oct 2020 00:34:27
	System	24 Oct 2020 00:34:27

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:52

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)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-23T20:34:19', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'bc20f34f-e390-4be1-92f1-61a57164cdf6'	System	24 Oct 2020 00:34:27
User entered 'No (N)'	System	24 Oct 2020 00:34:27

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-23T20:34:23', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'bc20f34f-e390-4be1-92f1-61a57164cdf6' User entered '23 Oct 2020 20:34'	System	24 Oct 2020 00:34:27
	System	24 Oct 2020 00:34:27

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '23 Oct 2020 12:00'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '24 Oct 2020 11:59'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	20 Oct 2020 14:10:15
User entered 'Day 5'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-24T15:58:41', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '17a6c385-c168-43c7-b68a-8cf97da81dfb' User entered 'None (0)'	System	24 Oct 2020 19:58:57
	System	24 Oct 2020 19:58:57

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-24T15:58:43', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '17a6c385-c168-43c7-b68a-8cf97da81dfb' User entered 'None (0)'	System	24 Oct 2020 19:58:57
	System	24 Oct 2020 19:58:57

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-24T15:58:44', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '17a6c385-c168-43c7-b68a-8cf97da81dfb' User entered 'None (0)'	System	24 Oct 2020 19:58:57
	System	24 Oct 2020 19:58:57

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-24T15:58:46', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '17a6c385-c168-43c7-b68a-8cf97da81dfb' User entered 'None (0)'	System	24 Oct 2020 19:58:57
	System	24 Oct 2020 19:58:57

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-24T15:58:48', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '17a6c385-c168-43c7-b68a-8cf97da81dfb' User entered 'None (0)'	System	24 Oct 2020 19:58:57
	System	24 Oct 2020 19:58:57

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-24T15:58:49', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '17a6c385-c168-43c7-b68a-8cf97da81dfb' User entered 'None (0)'	System	24 Oct 2020 19:58:57
	System	24 Oct 2020 19:58:57

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:52

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)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-24T15:58:51', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '17a6c385-c168-43c7-b68a-8cf97da81dfb' User entered 'No (N)'	System	24 Oct 2020 19:58:57
	System	24 Oct 2020 19:58:57

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-24T15:58:54', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '17a6c385-c168-43c7-b68a-8cf97da81dfb' User entered '24 Oct 2020 15:58'	System	24 Oct 2020 19:58:57
	System	24 Oct 2020 19:58:57

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '24 Oct 2020 12:00'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '25 Oct 2020 11:59'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	20 Oct 2020 14:10:15
User entered 'Day 6'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T00:34:36', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '21de5d6d-2cdc-46cd-8fad-82f29ad183ae' User entered 'None (0)'	System	26 Oct 2020 04:34:53
	System	26 Oct 2020 04:34:53

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T00:34:38', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '21de5d6d-2cdc-46cd-8fad-82f29ad183ae' User entered 'None (0)'	System	26 Oct 2020 04:34:53
	System	26 Oct 2020 04:34:53

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T00:34:40', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '21de5d6d-2cdc-46cd-8fad-82f29ad183ae' User entered 'None (0)'	System	26 Oct 2020 04:34:53
	System	26 Oct 2020 04:34:53

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T00:34:41', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '21de5d6d-2cdc-46cd-8fad-82f29ad183ae' User entered 'None (0)'	System	26 Oct 2020 04:34:53
	System	26 Oct 2020 04:34:53

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T00:34:43', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '21de5d6d-2cdc-46cd-8fad-82f29ad183ae' User entered 'None (0)'	System	26 Oct 2020 04:34:53
	System	26 Oct 2020 04:34:53

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T00:34:45', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '21de5d6d-2cdc-46cd-8fad-82f29ad183ae' User entered 'None (0)'	System	26 Oct 2020 04:34:53
	System	26 Oct 2020 04:34:53

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:52

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)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T00:34:47', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '21de5d6d-2cdc-46cd-8fad-82f29ad183ae' User entered 'No (N)'	System	26 Oct 2020 04:34:53
	System	26 Oct 2020 04:34:53

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T00:34:49', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '21de5d6d-2cdc-46cd-8fad-82f29ad183ae' User entered '26 Oct 2020 00:34'	System	26 Oct 2020 04:34:53
	System	26 Oct 2020 04:34:53

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '25 Oct 2020 12:00'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '26 Oct 2020 11:59'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
Data entry locked.	System	20 Oct 2020 14:10:15
User entered 'Day 7'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T19:01:46', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '30c962c8-e7ec-400b-b4f4-ff5c264595e6' User entered 'None (0)'	System	26 Oct 2020 23:02:09
	System	26 Oct 2020 23:02:09

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T19:01:48', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '30c962c8-e7ec-400b-b4f4-ff5c264595e6' User entered 'None (0)'	System	26 Oct 2020 23:02:09
	System	26 Oct 2020 23:02:09

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T19:01:50', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '30c962c8-e7ec-400b-b4f4-ff5c264595e6' User entered 'None (0)'	System	26 Oct 2020 23:02:09
	System	26 Oct 2020 23:02:09

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T19:01:53', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '30c962c8-e7ec-400b-b4f4-ff5c264595e6' User entered 'None (0)'	System	26 Oct 2020 23:02:09
	System	26 Oct 2020 23:02:09

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T19:01:55', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '30c962c8-e7ec-400b-b4f4-ff5c264595e6' User entered 'None (0)'	System	26 Oct 2020 23:02:09
	System	26 Oct 2020 23:02:09

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T19:01:57', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '30c962c8-e7ec-400b-b4f4-ff5c264595e6' User entered 'None (0)'	System	26 Oct 2020 23:02:09
	System	26 Oct 2020 23:02:09

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:52

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)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T19:02:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '30c962c8-e7ec-400b-b4f4-ff5c264595e6' User entered 'No (N)'	System	26 Oct 2020 23:02:09
	System	26 Oct 2020 23:02:09

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-10-26T19:02:04', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '30c962c8-e7ec-400b-b4f4-ff5c264595e6' User entered '26 Oct 2020 19:02'	System	26 Oct 2020 23:02:09
	System	26 Oct 2020 23:02:09

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '26 Oct 2020 12:00'	System	20 Oct 2020 14:10:15

US3702040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:18:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:52:10
User entered '27 Oct 2020 11:59'	System	20 Oct 2020 14:10:15

US3702040

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	09 Nov 2020 23:00:04

US3702040

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '29 Oct 2020'	Jiamin Li (b) (4)	09 Nov 2020 23:00:04

US3702040

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	09 Nov 2020 23:00:04

US3702040

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	09 Nov 2020 23:00:04

US3702040

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	09 Nov 2020 23:00:08

US3702040

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered 'I'	System	09 Nov 2020 23:00:08

US3702040

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	09 Nov 2020 23:00:30

US3702040

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '03 Nov 2020'	Jiamin Li (b) (4)	09 Nov 2020 23:00:30

US3702040

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	09 Nov 2020 23:00:30

US3702040

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	09 Nov 2020 23:00:30

US3702040

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	09 Nov 2020 23:00:34

US3702040

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered 'I'	System	09 Nov 2020 23:00:34

US3702040

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Dec 2020 14:42:51

US3702040

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '11 Nov 2020'	Jiamin Li (b) (4)	22 Dec 2020 14:42:51

US3702040

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	22 Dec 2020 14:42:51

US3702040

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	22 Dec 2020 14:42:51

US3702040

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Mia Crowley (b) (4)	17 Nov 2020 15:22:02

US3702040

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered 'I'	System	17 Nov 2020 15:22:02

US3702040

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 17NOV2020 is reported underVisit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 10:45:07
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 17NOV2020 is reported underVisit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	22 Dec 2020 14:44:07
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 17NOV2020 is reported underVisit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 05:45:39
User entered 'Yes (Y)'	Mia Crowley (b) (4)	17 Nov 2020 15:22:22

US3702040

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '17 Nov 2020'	Mia Crowley (b) (4)	17 Nov 2020 15:22:22

US3702040

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Clinic (Clinic)'	Mia Crowley (b) (4)	17 Nov 2020 15:22:22

US3702040

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered 'VISIT3'	System	17 Nov 2020 15:22:22

US3702040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Dec 2020 14:44:36

US3702040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '17 Nov 2020'	Jiamin Li (b) (4)	22 Dec 2020 14:44:36

US3702040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '10:37'	Jiamin Li (b) (4)	22 Dec 2020 14:44:36

US3702040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered '17 Nov 2020 10:37'	System	22 Dec 2020 14:44:36

US3702040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	12 Jan 2021 21:19:24
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Clinically insignificant per clinician.' (Site from System).	Jiamin Li (b) (4)	22 Dec 2020 14:44:44
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	22 Dec 2020 14:44:36
User entered '35.8' C	Jiamin Li (b) (4)	22 Dec 2020 14:44:36

US3702040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Other (Other)'	Jiamin Li (b) (4)	22 Dec 2020 14:44:36

US3702040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Temporal'	Jiamin Li (b) (4)	22 Dec 2020 14:44:36

US3702040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '70'	Jiamin Li (b) (4)	22 Dec 2020 14:44:36

US3702040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered 'bpm'	System	22 Dec 2020 14:44:36

US3702040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '16'	Jiamin Li (b) (4)	22 Dec 2020 14:44:36

US3702040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered 'breaths/min'	System	22 Dec 2020 14:44:36

US3702040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '125'	Jiamin Li (b) (4)	22 Dec 2020 14:44:36

US3702040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered 'mmHg'	System	22 Dec 2020 14:44:36

US3702040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '73'	Jiamin Li (b) (4)	22 Dec 2020 14:44:36

US3702040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered 'mmHg'	System	22 Dec 2020 14:44:36

US3702040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33

US3702040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33

US3702040

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Dec 2020 14:44:51

US3702040

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '17 Nov 2020'	Jiamin Li (b) (4)	22 Dec 2020 14:44:51

US3702040

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Dec 2020 14:45:21

US3702040

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '17 Nov 2020'	Jiamin Li (b) (4)	22 Dec 2020 14:45:21

US3702040

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:52

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '09:44'	Jiamin Li (b) (4)	22 Dec 2020 14:45:21

US3702040

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered '17 Nov 2020 09:44'	System	22 Dec 2020 14:45:21

US3702040

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Mia Crowley (b) (4)	17 Nov 2020 15:22:28

US3702040

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered 'I'	System	17 Nov 2020 15:22:28

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-11-28T17:59:13', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '99aa99e5-c74a-41ba-aa39-70c3e22bf9de' User entered 'No (N)'	System	28 Nov 2020 22:59:32
	System	28 Nov 2020 22:59:32

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-11-28T17:59:24', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '99aa99e5-c74a-41ba-aa39-70c3e22bf9de' User entered 'No (N)'	System	28 Nov 2020 22:59:32
	System	28 Nov 2020 22:59:32

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-11-28T17:59:28', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '99aa99e5-c74a-41ba-aa39-70c3e22bf9de' User entered '28 Nov 2020 17:59:28'	System	28 Nov 2020 22:59:32
	System	28 Nov 2020 22:59:32

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-12-04T14:24:43', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '9e6d8b21-f384-472d-bd7b-54d14a41951c' User entered 'No (N)'	System	04 Dec 2020 19:25:06
	System	04 Dec 2020 19:25:06

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-12-04T14:24:55', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '9e6d8b21-f384-472d-bd7b-54d14a41951c' User entered 'No (N)'	System	04 Dec 2020 19:25:06
	System	04 Dec 2020 19:25:06

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-12-04T14:25:02', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '9e6d8b21-f384-472d-bd7b-54d14a41951c' User entered '04 Dec 2020 14:25:02'	System	04 Dec 2020 19:25:06
	System	04 Dec 2020 19:25:06

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-12-12T17:59:14', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '50f35fcb-ed23-46eb-b862-75e152de949c' User entered 'No (N)'	System	12 Dec 2020 22:59:24
	System	12 Dec 2020 22:59:24

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-12-12T17:59:18', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '50f35fcb-ed23-46eb-b862-75e152de949c' User entered 'No (N)'	System	12 Dec 2020 22:59:24
	System	12 Dec 2020 22:59:24

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-12-12T17:59:22', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '50f35fcb-ed23-46eb-b862-75e152de949c' User entered '12 Dec 2020 17:59:22'	System	12 Dec 2020 22:59:24
	System	12 Dec 2020 22:59:24

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-12-20T11:59:13', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '26df5fbe-b4e9-45ad-b08a-2b7ddb98c680'	System	20 Dec 2020 16:59:55
User entered 'Yes (Y)'	System	20 Dec 2020 16:59:55

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-12-20T11:59:19', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '26df5fbe-b4e9-45ad-b08a-2b7ddb98c680'	System	20 Dec 2020 16:59:55
User entered 'No (N)'	System	20 Dec 2020 16:59:55

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-12-20T11:59:24', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '26df5fbe-b4e9-45ad-b08a-2b7ddb98c680'	System	20 Dec 2020 16:59:55
User entered 'No (N)'	System	20 Dec 2020 16:59:55

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-12-20T11:59:27', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '26df5fbe-b4e9-45ad-b08a-2b7ddb98c680'	System	20 Dec 2020 16:59:55
User entered 'Yes (Y)'	System	20 Dec 2020 16:59:55

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-12-20T11:59:39', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '26df5fbe-b4e9-45ad-b08a-2b7ddb98c680'	System	20 Dec 2020 16:59:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Dec 2020 16:59:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2020-12-20T11:59:47', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '26df5fbe-b4e9-45ad-b08a-2b7ddb98c680' User entered '20 Dec 2020 11:59:47'	System	20 Dec 2020 16:59:55
	System	20 Dec 2020 16:59:55

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 09:52:21

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 09:52:21

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-01-10T11:59:25', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '6e00ad87-c1ae-4af7-9852-c8b652ac137f'	System	10 Jan 2021 16:59:44
User entered 'No (N)'	System	10 Jan 2021 16:59:44

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-01-10T11:59:28', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '6e00ad87-c1ae-4af7-9852-c8b652ac137f'	System	10 Jan 2021 16:59:44
User entered 'No (N)'	System	10 Jan 2021 16:59:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-01-10T11:59:42', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '6e00ad87-c1ae-4af7-9852-c8b652ac137f' User entered '10 Jan 2021 11:59:42'	System	10 Jan 2021 16:59:44
	System	10 Jan 2021 16:59:44

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-01-15T12:00:47', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f2400c91-1a43-45e9-b710-42d54517afc0' User entered 'No (N)'	System	30 Jan 2021 23:34:44
	System	30 Jan 2021 23:34:44

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-01-15T12:00:52', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f2400c91-1a43-45e9-b710-42d54517afc0'	System	30 Jan 2021 23:34:44
User entered 'No (N)'	System	30 Jan 2021 23:34:44

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-01-15T12:00:57', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'f2400c91-1a43-45e9-b710-42d54517afc0' User entered '15 Jan 2021 12:00:57'	System	30 Jan 2021 23:34:44
	System	30 Jan 2021 23:34:44

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-01-30T18:34:47', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'fc4fa8d2-5337-4535-b96c-ca261e5e30cb' User entered 'No (N)'	System	30 Jan 2021 23:34:55
	System	30 Jan 2021 23:34:55

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-01-30T18:34:50', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'fc4fa8d2-5337-4535-b96c-ca261e5e30cb' User entered 'No (N)'	System	30 Jan 2021 23:34:55
	System	30 Jan 2021 23:34:55

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-01-30T18:34:53', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'fc4fa8d2-5337-4535-b96c-ca261e5e30cb' User entered '30 Jan 2021 18:34:53'	System	30 Jan 2021 23:34:55
	System	30 Jan 2021 23:34:55

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-02-12T12:00:23', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'a31e0c1b-4b95-4245-ba9f-bd0d8bbb7851'	System	12 Feb 2021 17:02:43
User entered 'No (N)'	System	12 Feb 2021 17:02:43

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-02-12T12:00:27', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'a31e0c1b-4b95-4245-ba9f-bd0d8bbb7851'	System	12 Feb 2021 17:02:43
User entered 'No (N)'	System	12 Feb 2021 17:02:43

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-02-12T12:00:30', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'a31e0c1b-4b95-4245-ba9f-bd0d8bbb7851'	System	12 Feb 2021 17:02:43
User entered '12 Feb 2021 12:00:30'	System	12 Feb 2021 17:02:43

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-02-19T14:40:43', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '37d7c8c9-0deb-4afa-9a77-2022b0d22e62' User entered 'No (N)'	System	19 Feb 2021 19:40:52
	System	19 Feb 2021 19:40:52

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-02-19T14:40:46', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '37d7c8c9-0deb-4afa-9a77-2022b0d22e62'	System	19 Feb 2021 19:40:52
User entered 'No (N)'	System	19 Feb 2021 19:40:52

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-02-19T14:40:49', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '37d7c8c9-0deb-4afa-9a77-2022b0d22e62' User entered '19 Feb 2021 14:40:49'	System	19 Feb 2021 19:40:52
	System	19 Feb 2021 19:40:52

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-02-28T08:47:11-05:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '2d03b758-092d-428c-9f6c-b37d545c2f71'	System	28 Feb 2021 13:47:24
User entered 'No (N)'	System	28 Feb 2021 13:47:24

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-02-28T08:47:15-05:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '2d03b758-092d-428c-9f6c-b37d545c2f71'	System	28 Feb 2021 13:47:24
User entered 'No (N)'	System	28 Feb 2021 13:47:24

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-02-28T08:47:19-05:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '2d03b758-092d-428c-9f6c-b37d545c2f71'	System	28 Feb 2021 13:47:24
User entered '28 Feb 2021 13:47:19'	System	28 Feb 2021 13:47:24

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-03-07T13:31:12-05:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '66d7daad-933e-41e1-9d76-c7c9f646c010'	System	07 Mar 2021 18:31:21
User entered 'No (N)'	System	07 Mar 2021 18:31:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-03-07T13:31:16-05:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '66d7daad-933e-41e1-9d76-c7c9f646c010'	System	07 Mar 2021 18:31:21
User entered 'No (N)'	System	07 Mar 2021 18:31:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-03-07T13:31:19-05:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '66d7daad-933e-41e1-9d76-c7c9f646c010'	System	07 Mar 2021 18:31:21
User entered '07 Mar 2021 13:31:19'	System	07 Mar 2021 18:31:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-03-19T12:07:04-04:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'ed5fd0ea-0c77-4f1e-aa21-d6f0163f3a25'	System	22 Mar 2021 15:31:41
User entered 'No (N)'	System	22 Mar 2021 15:31:41

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-03-19T12:07:07-04:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'ed5fd0ea-0c77-4f1e-aa21-d6f0163f3a25'	System	22 Mar 2021 15:31:41
User entered 'No (N)'	System	22 Mar 2021 15:31:41

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-03-19T12:07:10-04:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'ed5fd0ea-0c77-4f1e-aa21-d6f0163f3a25'	System	22 Mar 2021 15:31:41
User entered '19 Mar 2021 12:07:10'	System	22 Mar 2021 15:31:41

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-03-27T18:11:21-04:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '49a8e439-67dc-437f-a18b-fb743e4b1912'	System	27 Mar 2021 22:12:08
User entered 'No (N)'	System	27 Mar 2021 22:12:08

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-03-27T18:11:24-04:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '49a8e439-67dc-437f-a18b-fb743e4b1912'	System	27 Mar 2021 22:12:08
User entered 'No (N)'	System	27 Mar 2021 22:12:08

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-03-27T18:11:28-04:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '49a8e439-67dc-437f-a18b-fb743e4b1912'	System	27 Mar 2021 22:12:08
User entered '27 Mar 2021 18:11:28'	System	27 Mar 2021 22:12:08

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-04-04T11:59:19-04:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '9d6d3e5a-9c7e-44c6-8cb2-d518f5b2631c' User entered 'No (N)'	System	04 Apr 2021 15:59:28
	System	04 Apr 2021 15:59:28

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-04-04T11:59:22-04:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '9d6d3e5a-9c7e-44c6-8cb2-d518f5b2631c' User entered 'No (N)'	System	04 Apr 2021 15:59:28
	System	04 Apr 2021 15:59:28

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-04-04T11:59:25-04:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: '9d6d3e5a-9c7e-44c6-8cb2-d518f5b2631c' User entered '04 Apr 2021 11:59:25'	System	04 Apr 2021 15:59:28
	System	04 Apr 2021 15:59:28

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-04-16T12:00:16-04:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'ff185cab-8a18-4776-b499-a72ad98c0164'	System	24 Apr 2021 23:11:02
User entered 'No (N)'	System	24 Apr 2021 23:11:02

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-04-16T12:00:19-04:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'ff185cab-8a18-4776-b499-a72ad98c0164'	System	24 Apr 2021 23:11:02
User entered 'No (N)'	System	24 Apr 2021 23:11:02

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-04-16T12:00:21-04:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'ff185cab-8a18-4776-b499-a72ad98c0164'	System	24 Apr 2021 23:11:02
User entered '16 Apr 2021 12:00:21'	System	24 Apr 2021 23:11:02

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-04-24T19:11:01-04:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'd86d30ba-2001-4103-a984-b1ef750495a7'	System	30 Apr 2021 16:30:17
User entered 'No (N)'	System	30 Apr 2021 16:30:17

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-04-24T19:11:06-04:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'd86d30ba-2001-4103-a984-b1ef750495a7'	System	30 Apr 2021 16:30:17
User entered 'No (N)'	System	30 Apr 2021 16:30:17

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-04-24T19:11:09-04:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'd86d30ba-2001-4103-a984-b1ef750495a7'	System	30 Apr 2021 16:30:17
User entered '24 Apr 2021 19:11:09'	System	30 Apr 2021 16:30:17

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-04-30T12:19:40-04:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'b409ebf5-9a61-47b6-98c5-80f4fed23b69'	System	30 Apr 2021 16:30:46
User entered 'No (N)'	System	30 Apr 2021 16:30:46

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-04-30T12:19:42-04:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'b409ebf5-9a61-47b6-98c5-80f4fed23b69'	System	30 Apr 2021 16:30:46
User entered 'No (N)'	System	30 Apr 2021 16:30:46

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-04-30T12:20:44-04:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'b409ebf5-9a61-47b6-98c5-80f4fed23b69' User entered '30 Apr 2021 12:20:44'	System	30 Apr 2021 16:30:46
	System	30 Apr 2021 16:30:46

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '02 Nov 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '06 Nov 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '09 Nov 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '13 Nov 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '16 Nov 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '20 Nov 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '23 Nov 2022 00:01'	System	20 Nov 2020 09:52:21

US3702040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:52:21
Amendment Manager: User entered '27 Nov 2022 23:59'	System	20 Nov 2020 09:52:21

US3702040

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:18:52

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-02-28T08:46:46-05:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'a9157d02-4628-4ec2-b839-585ee5ed51be'	System	28 Feb 2021 13:47:15
User entered 'Yes (Y)'	System	28 Feb 2021 13:47:15

US3702040

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:18:52

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-02-28T08:46:58-05:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'a9157d02-4628-4ec2-b839-585ee5ed51be'	System	28 Feb 2021 13:47:15
User entered 'No (N)'	System	28 Feb 2021 13:47:15

US3702040

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:18:52

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300D0050-20D6-4363-820E-C8C0A8271F16)', Time: '2021-02-28T08:47:04-05:00', User OID: 'PatientReportedOutcome (US3702040)', ODM File OID: 'a9157d02-4628-4ec2-b839-585ee5ed51be' User entered '28 Feb 2021 13:47:04'	System	28 Feb 2021 13:47:15
	System	28 Feb 2021 13:47:15

US3702040

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:55:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Dec 2020 14:47:04

US3702040

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:55:17
User entered '17 Dec 2020'	Jiamin Li (b) (4)	22 Dec 2020 14:47:04

US3702040

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:55:17
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	22 Dec 2020 14:47:04

US3702040

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:55:17
User entered empty.	Jiamin Li (b) (4)	22 Dec 2020 14:47:04

US3702040

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:55:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Dec 2020 14:47:10

US3702040

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:33
User entered 'I'	System	22 Dec 2020 14:47:10

US3702040

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered 'Yes (Y)'	Jiamin Li (b) (4)	04 Feb 2021 02:27:03

US3702040

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered '19 Jan 2021'	Jiamin Li (b) (4)	04 Feb 2021 02:27:03

US3702040

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	04 Feb 2021 02:27:03

US3702040

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered empty.	Jiamin Li (b) (4)	04 Feb 2021 02:27:03

US3702040

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered 'Yes (Y)'	Jiamin Li (b) (4)	04 Feb 2021 02:27:17

US3702040

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:17
User entered 'I'	System	04 Feb 2021 02:27:17

US3702040

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered 'Yes (Y)'	Jiamin Li (b) (4)	09 Mar 2021 00:58:01

US3702040

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered '16 Feb 2021'	Jiamin Li (b) (4)	09 Mar 2021 00:58:01

US3702040

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	09 Mar 2021 00:58:01

US3702040

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered empty.	Jiamin Li (b) (4)	09 Mar 2021 00:58:01

US3702040

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered 'Yes (Y)'	Jiamin Li (b) (4)	09 Mar 2021 00:58:14

US3702040

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:17
User entered 'I'	System	09 Mar 2021 00:58:14

US3702040

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered 'Yes (Y)'	Jiamin Li (b) (4)	31 Mar 2021 00:37:29

US3702040

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered '19 Mar 2021'	Jiamin Li (b) (4)	31 Mar 2021 00:37:29

US3702040

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	31 Mar 2021 00:37:29

US3702040

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered empty.	Jiamin Li (b) (4)	31 Mar 2021 00:37:29

US3702040

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered 'Yes (Y)'	Jiamin Li (b) (4)	31 Mar 2021 00:37:19

US3702040

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:17
User entered 'I'	System	31 Mar 2021 00:37:19

US3702040

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:29:42
User entered 'Yes (Y)'	Caique Mello (b) (4) (b) (4)	19 Apr 2021 15:52:39

US3702040

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:29:42
User entered '19 Apr 2021'	Caique Mello (b) (4) (b) (4)	19 Apr 2021 15:52:39

US3702040

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:29:42
User entered 'Clinic (Clinic)'	Caique Mello (b) (4) (b) (4)	19 Apr 2021 15:52:39

US3702040

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	19 Apr 2021 15:52:39

US3702040

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:29:42
User entered 'Yes (Y)'	Caique Mello (b) (4) (b) (4)	19 Apr 2021 15:52:47

US3702040

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 15:52:47

US3702040

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

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 11JAN2021 for the Participant Decision Visit, however, there is no data recorded on the Immunogenicity Assessment form within this folder. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 16:26:46
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 11JAN2021 for the Participant Decision Visit, however, there is no data recorded on the Immunogenicity Assessment form within this folder. Please clarify and update as appropriate. ' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	04 Feb 2021 02:17:28
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 11JAN2021 for the Participant Decision Visit, however, there is no data recorded on the Immunogenicity Assessment form within this folder. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 19:54:16
User entered 'Yes (Y)'	Mia Crowley (b) (4)	11 Jan 2021 21:56:27

US3702040

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

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '11 Jan 2021'	Mia Crowley (b) (4)	11 Jan 2021 21:56:27

US3702040

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

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

[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 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Clinic (Clinic)'	Mia Crowley (b) (4)	11 Jan 2021 21:56:27

US3702040

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

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'UNBLND_DECIDE'	System	11 Jan 2021 21:56:27

US3702040

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

Form: Unblinding

Generated On: 10 Jun 2021 09:18:52

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '11 Jan 2021'	Mia Crowley (b) (4)	11 Jan 2021 21:56:47

US3702040

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

Form: Unblinding

Generated On: 10 Jun 2021 09:18:52

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '0'	Jiamin Li (b) (4)	09 Mar 2021 00:50:20
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:46:55

US3702040

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

Form: Unblinding

Generated On: 10 Jun 2021 09:18:52

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Yes (Y)'	Mia Crowley (b) (4)	11 Jan 2021 21:56:47

US3702040

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

Form: Unblinding

Generated On: 10 Jun 2021 09:18:52

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Amendment 6 or later (Amendment 6 or later)'	Jiamin Li (b) (4)	09 Mar 2021 00:50:20
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:46:55

US3702040

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

Form: Unblinding

Generated On: 10 Jun 2021 09:18:52

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '11 Jan 2021'	Mia Crowley (b) (4)	11 Jan 2021 21:56:47

US3702040

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

Form: Unblinding

Generated On: 10 Jun 2021 09:18:52

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Placebo (Placebo)'	Mia Crowley (b) (4)	11 Jan 2021 21:56:47

US3702040

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

Form: Unblinding

Generated On: 10 Jun 2021 09:18:52

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 15:22:33
User entered 'Placebo (Placebo)'	Mia Crowley (b) (4)	11 Jan 2021 21:56:47

US3702040

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

Form: Unblinding

Generated On: 10 Jun 2021 09:18:52

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 15:22:33
User entered 'Placebo (Placebo)'	Mia Crowley (b) (4)	11 Jan 2021 21:56:47

US3702040

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

Form: Unblinding

Generated On: 10 Jun 2021 09:18:52

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Yes (Y)'	Mia Crowley (b) (4)	11 Jan 2021 21:56:47

US3702040

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

Form: Unblinding

Generated On: 10 Jun 2021 09:18:52

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered '1'	System	11 Jan 2021 21:56:47

US3702040

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

Form: Unblinding

Generated On: 10 Jun 2021 09:18:52

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'I'	System	11 Jan 2021 21:56:47

US3702040

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:18:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered '170.1' cm	Jiamin Li (b) (4)	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:18:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered '84.2' kg	Jiamin Li (b) (4)	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered '29.10070'	System	04 Feb 2021 02:24:06
DataPoint set to visible.	System	11 Jan 2021 21:56:47

US3702040

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:18:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered '170.1' cm	Jiamin Li (b) (4)	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:18:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered '84.2' kg	Jiamin Li (b) (4)	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:18:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered '29.10070'	System	04 Feb 2021 02:24:06
DataPoint set to visible.	System	11 Jan 2021 21:56:47

US3702040

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User accepted default value 'Pre-Dose (PREDOSE)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered 'Yes (Y)'	Jiamin Li (b) (4)	04 Feb 2021 02:24:06

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered '11 Jan 2021'	Jiamin Li (b) (4)	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered '10:07'	Jiamin Li (b) (4)	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered '11 Jan 2021 10:07'	System	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	04 Feb 2021 16:08:10
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Clinically insignificant per clinician' (Site from System).	Jiamin Li (b) (4)	04 Feb 2021 02:24:29
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	04 Feb 2021 02:24:06
User entered '96.1' F	Jiamin Li (b) (4)	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered 'Other (Other)'	Jiamin Li (b) (4)	04 Feb 2021 02:24:06

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered 'Temporal'	Jiamin Li (b) (4)	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered '95'	Jiamin Li (b) (4)	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'bpm'	System	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered '16'	Jiamin Li (b) (4)	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'breaths/min'	System	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered '113'	Jiamin Li (b) (4)	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'mmHg'	System	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered '72'	Jiamin Li (b) (4)	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'mmHg'	System	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:18:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered '170.1' cm	Jiamin Li (b) (4)	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:18:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered '84.2' kg	Jiamin Li (b) (4)	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:18:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered '29.10070'	System	04 Feb 2021 02:24:06
DataPoint set to visible.	System	11 Jan 2021 21:56:47

US3702040

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User accepted default value 'Post-Dose (POSTDOSE)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:24:06

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered 'Yes (Y)'	Jiamin Li (b) (4)	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered '11 Jan 2021'	Jiamin Li (b) (4)	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	04 Feb 2021 12:48:57
Query 'Data is required. Please provide.' answered with 'Information not captured' (Site from System).	Jiamin Li (b) (4)	04 Feb 2021 02:25:15
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Feb 2021 02:24:06
User entered empty.	Jiamin Li (b) (4)	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered empty.	System	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered '36.8' C	Jiamin Li (b) (4)	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered 'Other (Other)'	Jiamin Li (b) (4)	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered 'Temporal'	Jiamin Li (b) (4)	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered '72'	Jiamin Li (b) (4)	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'bpm'	System	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	04 Feb 2021 12:48:59
Query 'Data is required. Please provide.' answered with 'Information not captured' (Site from System).	Jiamin Li (b) (4)	04 Feb 2021 02:25:20
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Feb 2021 02:24:06
User entered empty.	Jiamin Li (b) (4)	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered empty.	System	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered '124'	Jiamin Li (b) (4)	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'mmHg'	System	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered '88'	Jiamin Li (b) (4)	04 Feb 2021 02:24:06

US3702040

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'mmHg'	System	04 Feb 2021 02:24:06

US3702040

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Yes (Y)'	Jiamin Li (b) (4)	04 Feb 2021 02:21:10

US3702040

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '11 Jan 2021'	Jiamin Li (b) (4)	04 Feb 2021 02:21:10

US3702040

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

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 11-Jan-2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 10:48:10
Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 11-Jan-2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	04 Feb 2021 02:17:11
User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 11-Jan-2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 10:17:35
User entered 'Yes (Y)'	Mia Crowley (b) (4)	11 Jan 2021 21:57:10

US3702040

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

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Mia Crowley (b) (4)	11 Jan 2021 21:57:10

US3702040

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

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

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)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Mia Crowley (b) (4)	11 Jan 2021 21:57:10

US3702040

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

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'mRNA-1273'	System	11 Jan 2021 21:57:10
DataPoint set to visible.	System	11 Jan 2021 21:56:47

US3702040

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

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '11 Jan 2021'	Mia Crowley (b) (4)	11 Jan 2021 21:57:10

US3702040

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

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '11:13'	Mia Crowley (b) (4)	11 Jan 2021 21:57:10

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

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered '11 Jan 2021 11:13'	System	11 Jan 2021 21:57:10

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

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Left Arm (LEFT ARM)'	Mia Crowley (b) (4)	11 Jan 2021 21:57:10

US3702040

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

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'ONCE'	System	11 Jan 2021 21:57:10

US3702040

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

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'INTRAMUSCULAR'	System	11 Jan 2021 21:57:10

US3702040

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Yes (Y)'	Jiamin Li (b) (4)	04 Feb 2021 02:25:49

US3702040

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '11 Jan 2021'	Jiamin Li (b) (4)	04 Feb 2021 02:25:49

US3702040

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:52

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '10:39'	Jiamin Li (b) (4)	04 Feb 2021 02:25:49

US3702040

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered '11 Jan 2021 10:39'	System	04 Feb 2021 02:25:49

US3702040

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:18:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Yes (Y)'	Jiamin Li (b) (4)	04 Feb 2021 02:25:34

US3702040

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '11 Jan 2021'	Jiamin Li (b) (4)	04 Feb 2021 02:25:34

US3702040

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:18:52

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '11:11'	Jiamin Li (b) (4)	04 Feb 2021 02:25:34

US3702040

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered '11 Jan 2021 11:11'	System	04 Feb 2021 02:25:34

US3702040

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

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Yes (Y)'	Mia Crowley (b) (4)	11 Jan 2021 21:57:16

US3702040

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

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'I'	System	11 Jan 2021 21:57:16

US3702040

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered 'Yes (Y)'	Jiamin Li (b) (4)	04 Feb 2021 02:26:46

US3702040

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered '19 Jan 2021'	Jiamin Li (b) (4)	04 Feb 2021 02:26:46

US3702040

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	04 Feb 2021 02:26:46

US3702040

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered empty.	Jiamin Li (b) (4)	04 Feb 2021 02:26:46

US3702040

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered 'Yes (Y)'	Jiamin Li (b) (4)	04 Feb 2021 02:26:53

US3702040

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:11
User entered 'I'	System	04 Feb 2021 02:26:53

US3702040

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:11
User entered '1'	System	04 Feb 2021 02:26:53
DataPoint set to visible.	System	04 Feb 2021 02:26:53

US3702040

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Yes (Y)'	Caique Mello (b) (4)	08 Feb 2021 15:11:38

US3702040

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User closed query 'Per GCL Lab Recon: Sample was reported under Visit 3 OL-D57 dated 11Mar2021 in PPD Central lab; however Visit is blank in EDC. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 03:04:15
Query 'Per GCL Lab Recon: Sample was reported under Visit 3 OL-D57 dated 11Mar2021 in PPD Central lab; however Visit is blank in EDC. Please reconcile.' answered with 'Visit entered in EDC' (Site from DM).	Jiamin Li (b) (4)	10 Apr 2021 12:28:34
User opened query 'Per GCL Lab Recon: Sample was reported under Visit 3 OL-D57 dated 11Mar2021 in PPD Central lab; however Visit is blank in EDC. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 19:33:57
User entered '08 Feb 2021'	Caique Mello (b) (4)	08 Feb 2021 15:11:38

US3702040

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

[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 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Clinic (Clinic)'	Caique Mello (b) (4)	08 Feb 2021 15:11:38

US3702040

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'OLD29'	System	08 Feb 2021 15:11:38

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User accepted default value 'Pre-Dose (PREDOSE)'	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Yes (Y)'	Jiamin Li (b) (4)	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '08 Feb 2021'	Jiamin Li (b) (4)	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '09:33'	Jiamin Li (b) (4)	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered '08 Feb 2021 09:33'	System	09 Mar 2021 00:55:06

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '36.6' C	Jiamin Li (b) (4)	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Oral (Oral)'	Jiamin Li (b) (4)	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4)	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '77'	Jiamin Li (b) (4)	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'bpm'	System	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '16'	Jiamin Li (b) (4)	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'breaths/min'	System	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '125'	Jiamin Li (b) (4)	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'mmHg'	System	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '88'	Jiamin Li (b) (4)	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'mmHg'	System	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User accepted default value 'Post-Dose (POSTDOSE)'	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Yes (Y)'	Jiamin Li (b) (4)	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '08 Feb 2021'	Jiamin Li (b) (4)	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '11:03'	Jiamin Li (b) (4)	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered '08 Feb 2021 11:03'	System	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '36.8' C	Jiamin Li (b) (4)	09 Mar 2021 00:55:06

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Other (Other)'	Jiamin Li (b) (4)	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Information not specified'	Jiamin Li (b) (4)	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '67'	Jiamin Li (b) (4)	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'bpm'	System	09 Mar 2021 00:55:06

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '16'	Jiamin Li (b) (4)	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'breaths/min'	System	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '125'	Jiamin Li (b) (4)	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'mmHg'	System	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '86'	Jiamin Li (b) (4)	09 Mar 2021 00:55:06

US3702040

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'mmHg'	System	09 Mar 2021 00:55:06

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Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Yes (Y)'	Jiamin Li (b) (4)	09 Mar 2021 00:55:22

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Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '08 Feb 2021'	Jiamin Li (b) (4)	09 Mar 2021 00:55:22

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Yes (Y)'	Caique Mello (b) (4)	08 Feb 2021 15:45:28

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Caique Mello (b) (4)	08 Feb 2021 15:45:28

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

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)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Caique Mello (b) (4)	08 Feb 2021 15:45:28

US3702040

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'mRNA-1273'	System	08 Feb 2021 15:45:28
DataPoint set to visible.	System	04 Feb 2021 02:26:53

US3702040

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '08 Feb 2021'	Caique Mello (b) (4)	08 Feb 2021 15:45:28

US3702040

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '10:30'	Caique Mello (b) (4)	08 Feb 2021 15:45:28

US3702040

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered '08 Feb 2021 10:30'	System	08 Feb 2021 15:45:28

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Left Arm (LEFT ARM)'	Caique Mello (b) (4)	08 Feb 2021 15:45:28

US3702040

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'ONCE'	System	08 Feb 2021 15:45:28

US3702040

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:52

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'INTRAMUSCULAR'	System	08 Feb 2021 15:45:28

US3702040

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Yes (Y)'	Jiamin Li (b) (4)	09 Mar 2021 00:55:27

US3702040

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:58:04
User entered 'I'	System	09 Mar 2021 00:55:27

US3702040

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:31:59
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered 'Yes (Y)'	Jiamin Li (b) (4)	09 Mar 2021 00:57:43

US3702040

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:31:59
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered '16 Feb 2021'	Jiamin Li (b) (4)	09 Mar 2021 00:57:43

US3702040

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:31:59
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	09 Mar 2021 00:57:43

US3702040

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:18:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:31:59
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered empty.	Jiamin Li (b) (4)	09 Mar 2021 00:57:43

US3702040

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:31:59
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:28:48
User entered 'Yes (Y)'	Jiamin Li (b) (4)	09 Mar 2021 00:57:48

US3702040

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:31:59
User entered 'I'	System	09 Mar 2021 00:57:48

US3702040

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:21:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Yes (Y)'	Jiamin Li (b) (4)	24 Mar 2021 16:16:50

US3702040

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:21:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '11 Mar 2021'	Jiamin Li (b) (4)	24 Mar 2021 16:16:50

US3702040

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:21:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Clinic (Clinic)'	Jiamin Li (b) (4)	24 Mar 2021 16:16:50

US3702040

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:21:29
User entered 'OLD57'	System	24 Mar 2021 16:16:50

US3702040

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:21:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Yes (Y)'	Jiamin Li (b) (4)	24 Mar 2021 16:17:07

US3702040

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:21:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '11 Mar 2021'	Jiamin Li (b) (4)	24 Mar 2021 16:17:07

US3702040

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:21:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '13:10'	Jiamin Li (b) (4)	24 Mar 2021 16:17:07

US3702040

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:21:29
User entered '11 Mar 2021 13:10'	System	24 Mar 2021 16:17:07

US3702040

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:21:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '37.1' C	Jiamin Li (b) (4)	24 Mar 2021 16:17:07

US3702040

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:21:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Oral (Oral)'	Jiamin Li (b) (4)	24 Mar 2021 16:17:07

US3702040

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:21:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4)	24 Mar 2021 16:17:07

US3702040

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:21:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '66'	Jiamin Li (b) (4)	24 Mar 2021 16:17:07

US3702040

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:21:29
User entered 'bpm'	System	24 Mar 2021 16:17:07

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:21:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '16'	Jiamin Li (b) (4)	24 Mar 2021 16:17:07

US3702040

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:21:29
User entered 'breaths/min'	System	24 Mar 2021 16:17:07

US3702040

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:21:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '129'	Jiamin Li (b) (4)	24 Mar 2021 16:17:07

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:21:29
User entered 'mmHg'	System	24 Mar 2021 16:17:07

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:21:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '83'	Jiamin Li (b) (4)	24 Mar 2021 16:17:07

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:21:29
User entered 'mmHg'	System	24 Mar 2021 16:17:07

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:21:29

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:52

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:21:29

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Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:21:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Yes (Y)'	Jiamin Li (b) (4)	24 Mar 2021 16:17:12

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Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:21:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '11 Mar 2021'	Jiamin Li (b) (4)	24 Mar 2021 16:17:12

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:21:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Yes (Y)'	Jiamin Li (b) (4)	24 Mar 2021 16:17:27

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:21:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '11 Mar 2021'	Jiamin Li (b) (4)	24 Mar 2021 16:17:27

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:52

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:21:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '13:36'	Jiamin Li (b) (4)	24 Mar 2021 16:17:27

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:21:29
User entered '11 Mar 2021 13:36'	System	24 Mar 2021 16:17:27

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:18:52

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:36:41
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Oct 2020 21:24:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User closed query 'Per DM CLR: Please provide the specific location of joint pain (eg, generalized arthralgia knee joint pain, shoulder joint pain, etc.) Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 02:51:03
Query 'Per DM CLR: Please provide the specific location of joint pain (eg, generalized arthralgia knee joint pain, shoulder joint pain, etc.) Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'Generalized joint pain ' (Site from DM).	Jiamin Li (b) (4)	09 Mar 2021 00:51:13
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 16:54:13
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'Assessed' (Site from DM).	Jiamin Li (b) (4)	22 Dec 2020 14:41:42
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 20:48:42
User opened query 'Per DM CLR: Please provide the specific location of joint pain (eg, generalized arthralgia knee joint pain, shoulder joint pain, etc.) Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 05:47:36
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint pain - version MedDRA\23.0.	Coder Import (b) (4)	12 Oct 2020 22:15:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. Data point term sent to Coder	Coder Import (b) (4) (b) (4) System	12 Oct 2020 22:15:20 12 Oct 2020 21:25:14
User entered 'Joint pain (eDiary)'	Jiamin Li (b) (4) (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered 'No (N)'	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User closed query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 05:42:19
Query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	24 Nov 2020 21:19:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	24 Nov 2020 21:19:02
User opened query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 05:47:55
User entered 'No (N)'	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered 'No (N)'	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered '25 Sep 2020'	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User entered empty.	System	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered 'No (N)'	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered '30 Sep 2020'	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User entered empty.	System	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered 'No (N)'	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered 'Related (RELATED)'	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered 'None (NONE)'	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered 'I'	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 21:25:07

US3702040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User entered '0'	System	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45
User entered '0'	System	12 Oct 2020 21:25:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary hesitation, LLT: Urinary hesitancy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 02:21:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 02:21:36
Data point term sent to Coder	System	04 Feb 2021 02:20:26
User entered 'Urinary hesitancy'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:01
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '01 Nov 2020'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 21:13:43
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'Ongoing' (Site from DM).	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:51:26
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 03:30:50
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered 'None (NONE)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '1'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Feb 2021 02:19:54

US3702040

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 02:20:01
User entered '0'	System	04 Feb 2021 02:19:54

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
	(b) (4)	
User coded data point as SOC: Investigations, HLG: Cytogenetic investigations, HLT: Cell marker analyses, PT: Prostatic specific antigen increased, LLT: PSA increased - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 18:56:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 18:56:51
Data point term sent to Coder	System	04 Feb 2021 02:21:27
User entered 'Unknown reproductive system disorder (elevated PSA)'	Jiamin Li (b) (4)	04 Feb 2021 02:20:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '16 Dec 2020'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 02:20:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

US3702040

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 02:20:40

US3702040

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

US3702040

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

US3702040

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

US3702040

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

US3702040

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

US3702040

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

US3702040

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

US3702040

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

US3702040

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

US3702040

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

US3702040

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

US3702040

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

US3702040

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

US3702040

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered 'None (NONE)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

US3702040

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '1'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

US3702040

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

US3702040

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

US3702040

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

US3702040

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

US3702040

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:20:40

US3702040

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Feb 2021 02:20:40

US3702040

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Feb 2021 02:20:40

US3702040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:36
User entered 'USA-US133-2021-mRNA-1273-P301000004'	System	09 Mar 2021 14:49:32
User entered 'New'	(b) (4), (b) (6)	09 Mar 2021 14:49:32

US3702040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 00:52:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 00:52:46
Data point term sent to Coder	System	09 Mar 2021 00:52:10
User entered 'Prostate cancer'	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:04

US3702040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:04

US3702040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:04

US3702040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:04

US3702040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '26 Jan 2021'	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:04

US3702040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:04

US3702040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 00:52:04

US3702040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:04

US3702040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 16:35:56
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 13:29:19
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' answered with 'Confirmed event is still ongoing' (Site from Safety).	Jiamin Li (b) (4) (b) (4)	24 Mar 2021 16:19:13
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 20:10:46
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:04

US3702040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:04

US3702040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 00:52:04

US3702040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered 'Grade 4 (Grade 4)'	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:04

US3702040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
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	09 Mar 2021 00:52:41
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	09 Mar 2021 00:52:17
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System).	System	09 Mar 2021 00:52:17
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	09 Mar 2021 00:52:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:17
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	09 Mar 2021 00:52:04
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:04

US3702040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:04

US3702040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Jiamin Li (b) (4)	09 Mar 2021 00:52:41
	(b) (4)	
User entered '0'	Jiamin Li (b) (4)	09 Mar 2021 00:52:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:04

US3702040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:04

US3702040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:04

US3702040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:04

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:04

US3702040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:04

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:04

US3702040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:04

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:04

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:04

US3702040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 11 Jan 2021, then event occurred).' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 14:35:07
Query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 11 Jan 2021, then event occurred).' answered with 'Updated' (Site from Safety).	Jiamin Li (b) (4)	31 Mar 2021 00:38:19
Signature has been broken.	(b) (4)	31 Mar 2021 00:38:13
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Jiamin Li (b) (4)	31 Mar 2021 00:38:13
User opened query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 11 Jan 2021, then event occurred).' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 20:10:29
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered 'Not Applicable (NOT APPLICABLE)'	Jiamin Li (b) (4)	09 Mar 2021 00:52:04

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:04

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '1'	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:04

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:04

US3702040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 01:52:35
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'Event has not stabilized and patient is pending another treatment' (Site from Safety).	Jiamin Li (b) (4) (b) (4)	13 Apr 2021 13:07:01
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 20:11:06
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:04

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:52:04

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = Gallstones. Review if this finding is to be recorded as a separate AE event. If so, please update AE ecrf. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 19:18:47
User closed query 'Per DM CLR: Narrative = LUPRON INJECTIONS IN MAR 2021. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 19:18:40
User closed query 'Per DM CLR: Narrative = FIRMAGON 240MG, SINGLE SC COURSE. However, this does not correspond to the dose and route recorded in the CM eCRF. Please review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 19:18:38
Query 'Per DM CLR: Narrative = LUPRON INJECTIONS IN MAR 2021. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. Otherwise, clarify.' answered with 'Injection noted in con-med log.' (Site from DM).	Jiamin Li (b) (4) (b) (4)	13 Apr 2021 16:31:27
Query 'Per DM CLR: Narrative = FIRMAGON 240MG, SINGLE SC COURSE. However, this does not correspond to the dose and route recorded in the CM eCRF. Please review and reconcile data as appropriate.' answered with 'Narrative updated to 120mg.' (Site from DM).	Jiamin Li (b) (4) (b) (4)	13 Apr 2021 16:30:45
Signature has been broken.	Jiamin Li (b) (4) (b) (4)	13 Apr 2021 16:30:26

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Narrative](#)

Audit	User	Time (GMT)
User entered '59 YEAR OLD AFRICAN AMERICAN MALE SOUGHT OUT A UROLOGY CONSULT AFTER AN ELEVATED PSA RESULT ON ROUTINE SCREENING (RESULTS BELOW) IN ADDITIONAL TO NEW ONSET FREQUENCY AND NOCTURIA. HE HAS A (b) (6) FAMILY HISTORY OF PROSTATE CANCER. A RADIOLOGICAL WORK-UP WAS SUPPORTIVE OF THE CONFIRMED BIOPSY FINDING 26 JAN 2021 OF PROSTATE ADENOCARCINOMA (GLEASON STAGE 9). HE IS SCHEDULED TO HAVE A COMPLETE RADICAL PROSTATECTOMY IN APR 2021. ON 5 FEB 2021 HE STARTED FIRMAGON 120MG, SINGLE SC COURSE, TO BE FOLLOWED BY LUPRON INJECTIONS IN MAR 2021. HIS BONE SCAN 1 FEB 2021 FOUND NO EVIDENCE OF METASTASIS. PSA VALUES 1/5/2020 54 1/1/2020 56.03 ADDITIONAL RADIOLOGICAL SUMMARY: CT ABDOMEN PELVIS WITH AND WITHOUT IV CONTRAST 1 FEB 2021 IMPRESSION: ASYMMETRICALLY ENLARGED PROSTATE GLAND. NORMAL BLADDER AND UPPER TRACTS. GALLSTONES MRI PROSTATE WITH AND WITHOUT IV CONTRAST 16 JAN 2021 39 X 33 MM PREDOMINANTLY LEFT (CROSSING INTO RIGHT) THROUGHOUT TRANSVERSE PLANE MIDGLAND (EXTENDING FROM BASE TO APEX) TRANSITION ZONE LESION. PI-RADS 5, VERY HIGH (CLINICALLY SIGNIFICANT CANCER HIGHLY LIKELY). 16 X 9 MM LEFT ANTERIOR BASE (EXTENDING TO MIDGLAND) PERIPHERAL ZONE LESION. PI-RADS 5, VERY HIGH (CLINICALLY SIGNIFICANT CANCER HIGHLY LIKELY). 27 X 22 MM LEFT POSTEROMEDIAL BASE CENTRAL LESION. PI-RADS 5, VERY	Jiamin Li (b) (4) (b) (4)	13 Apr 2021 16:30:26

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Narrative](#)

Audit	User	Time (GMT)
HIGH (CLINICALLY SIGNIFICANT CANCER HIGHLY LIKELY). THERE IS OVERLYING GROSS EXTRAPROSTATIC EXTENSION INTO THE LEFT SEMINAL VESICLE. NO PELVIC LYMPHADENOPATHY.' reason for change: Data Entry Error		
Query 'Per DM CLR: Narrative = Gallstones. Review if this finding is to be recorded as a separate AE event. If so, please update AE ecrf. Else, clarify.' answered with 'Confirmed per clinician that it should not be recorded as a separate AE event. Likely an incidental finding on the CT scan.' (Site from DM).	Jiamin Li (b) (4)	13 Apr 2021 16:29:46
User opened query 'Per DM CLR: Narrative = Gallstones. Review if this finding is to be recorded as a separate AE event. If so, please update AE ecrf. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 02:42:39
User opened query 'Per DM CLR: Narrative = LUPRON INJECTIONS IN MAR 2021. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 01:52:10
User opened query 'Per DM CLR: Narrative = FIRMAGON 240MG, SINGLE SC COURSE. However, this does not correspond to the dose and route recorded in the CM eCRF. Please review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 01:52:04
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Narrative](#)

Audit	User	Time (GMT)
User entered '59 year old African American male sought out a urology consult after an elevated PSA result on routine screening (results below) in addition to new onset frequency and nocturia. He has a (b) (6) family history of prostate cancer. A radiological work-up was supportive of the confirmed biopsy finding 26 JAN 2021 of prostate adenocarcinoma (Gleason stage 9). He is scheduled to have a complete radical prostatectomy in APR 2021. On 5 FEB 2021 he started firmagon 240mg, single SC course, to be followed by lupron injections in MAR 2021. His bone scan 1 FEB 2021 found no evidence of metastasis. PSA values 1/5/2020 54 1/1/2020 56.03 Additional radiological summary: CT ABDOMEN PELVIS WITH AND WITHOUT IV CONTRAST 1 FEB 2021 IMPRESSION: Asymmetrically enlarged prostate gland. Normal bladder and upper tracts. Gallstones MRI PROSTATE WITH AND WITHOUT IV CONTRAST 16 JAN 2021 39 x 33 mm predominantly left (crossing into right) throughout transverse plane midgland (extending from base to apex) transition zone lesion. PI-RADS 5, very high (clinically significant cancer highly likely). 16 x 9 mm left anterior base (extending to midgland) peripheral zone lesion. PI-RADS 5, very high (clinically significant cancer highly likely). 27 x 22 mm left posteromedial base central lesion. PI-RADS 5, very high (clinically significant cancer highly likely). There is overlying gross extraprostatic extension into the left seminal vesicle. No pelvic lymphadenopathy.' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:55:53
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	09 Mar 2021 00:54:20
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	09 Mar 2021 00:54:20

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Narrative](#)

Audit	User	Time (GMT)
User entered 'New dx of prostate Ca and has started therapy with a Gonadotropin-releasing hormone antagonist, firmagon by SC injection this past Friday 2/5/21 and is scheduled to have a radical prostatectomy in APR 2021. Care at NYU. Plan to start lupron next month.' reason for change: Data Entry Error	Jiamin Li (b) (4)	09 Mar 2021 00:54:20
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	09 Mar 2021 00:52:17
User entered empty.	Jiamin Li (b) (4)	09 Mar 2021 00:52:04

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Mar 2021 00:52:17
User entered '0'	System	09 Mar 2021 00:52:04

US3702040

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Mar 2021 00:52:04

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User coded data point as SOC: General disorders and administration site conditions, HLGT: Body temperature conditions, HLT: Febrile disorders, PT: Pyrexia, LLT: Fever - version MedDRA\\23.0.	Coder Import (b) (4)	09 Mar 2021 00:57:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Mar 2021 00:57:51
Data point term sent to Coder	System	09 Mar 2021 00:57:11
User entered 'Fever (100.2 F)'	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered 'No (N)'	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered 'No (N)'	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered 'No (N)'	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered '09 Feb 2021'	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	10 Mar 2021 02:51:19
Query 'Data is required. Please provide.' answered with 'Information not provided by pt' (Site from System).	Jiamin Li (b) (4)	09 Mar 2021 00:56:50
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Mar 2021 00:56:40
User entered empty.	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User entered empty.	System	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered 'No (N)'	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered '09 Feb 2021'	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	10 Mar 2021 02:51:21
Query 'Data is required. Please provide.' answered with 'Information not provided by pt' (Site from System).	Jiamin Li (b) (4)	09 Mar 2021 00:56:48
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Mar 2021 00:56:40
User entered empty.	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User entered empty.	System	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered 'No (N)'	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered 'Related (RELATED)'	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered 'Not Applicable (NOT APPLICABLE)'	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered 'I'	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered '0'	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:43:51
User entered empty.	Jiamin Li (b) (4)	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User entered '0'	System	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51
User entered '0'	System	09 Mar 2021 00:56:40

US3702040

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:51

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:36:41
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User closed query 'Per CDM: Subject recorded as receiving facial injections but injection is not recorded on MH or CM CRF, please clarify or reconcile.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 19:20:40
Query 'Per CDM: Subject recorded as receiving facial injections but injection is not recorded on MH or CM CRF, please clarify or reconcile.' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	13 Apr 2021 16:28:05
User opened query 'Per CDM: Subject recorded as receiving facial injections but injection is not recorded on MH or CM CRF, please clarify or reconcile.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 14:50:18
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 14:50:18
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	10 Apr 2021 12:26:47
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:52:43

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:18:52

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:16:01

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: CHOLECALCIFEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 18:17:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 18:17:52
Data point term sent to Coder	System	25 Sep 2020 18:17:13
User entered 'Cholecalciferol'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:16:35

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:16:35

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'Vitamin deficiency'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:16:35

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered '125'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:16:35

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'ug (ug)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:16:35

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:16:35

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'every week (QS)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:16:35

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:16:35

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'Oral (ORAL)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:16:35

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:16:35

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered '01 Jan 2019'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:16:35

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered '0'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:16:35

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:16:35

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:16:35

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:16:35

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 18:16:35

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 18:16:35

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	25 Sep 2020 18:16:35

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:18:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: SEMAGLUTIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 10:56:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 10:56:39
Data point term sent to Coder	System	25 Sep 2020 18:19:22
User entered 'Semaglutide'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:19:15

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:18:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:19:15

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:18:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'Obesity'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:19:15

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:18:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered '0.25 or 0.5'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:19:15

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:18:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:19:15

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:18:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:19:15

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:18:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'unknown (UNKNOWN)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:19:15

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:18:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:19:15

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:18:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:19:15

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:18:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:19:15

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered '01 Jan 2020'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:19:15

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:18:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered '0'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:19:15

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:18:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:19:15

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:18:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:19:15

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:18:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:19:15

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:18:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 18:19:15

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:18:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 18:19:15

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:18:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 18:19:15

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:18:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VILAZODONE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 08:59:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 08:59:42
Data point term sent to Coder	System	25 Sep 2020 18:20:25
User entered 'Vilazodone HCl'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:20:00

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:18:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:20:00

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:18:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'Depression'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:20:00

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:18:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered '40'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:20:00

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:18:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:20:00

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:18:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:20:00

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:18:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'unknown (UNKNOWN)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:20:00

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:18:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:20:00

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:18:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'Oral (ORAL)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:20:00

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:18:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:20:00

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered '01 Jan 2019'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:20:00

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:18:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered '0'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:20:00

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:18:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:20:00

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:18:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:20:00

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:18:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 18:20:00

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:18:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 18:20:00

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:18:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 18:20:00

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:18:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 18:20:00

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:18:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: OTHER DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, PRODUCT: TADALAFIL, PRODUCTSYNONYM: CIALIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 14:55:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 14:55:45
Data point term sent to Coder	System	04 Feb 2021 02:19:25
User entered 'Cialis'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:18:56

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:18:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:18:56

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:18:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'Urinary hesitancy'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:18:56

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:18:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered '5'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:18:56

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:18:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:18:56

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:18:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:18:56

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:18:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'once daily (QD)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:18:56

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:18:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:18:56

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:18:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'Oral (ORAL)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:18:56

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:18:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:18:56

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered '01 Nov 2020'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:18:56

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:18:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered '0'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:18:56

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:18:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:18:56

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:18:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:18:56

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:18:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:18:56

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:18:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 02:18:56

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:18:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 02:18:56

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:18:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Feb 2021 02:18:56

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:18:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 10:24:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 10:24:44
Data point term sent to Coder	System	04 Feb 2021 02:19:26
User entered 'Amoxicillin'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:19

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:18:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:19

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:18:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'Oral surgery prophylaxis'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:19

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:18:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered '500'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:19

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:18:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:19

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:18:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:19

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:18:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'twice daily (BID)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:19

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:18:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:19

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:18:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'Oral (ORAL)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:19

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:18:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:19

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered '09 Jan 2021'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:19

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:18:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered '0'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:19

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:18:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:19

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:18:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:19

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:18:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 02:19:19

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:18:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Feb 2021 02:19:19

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:18:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 02:19:19

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:18:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Feb 2021 02:19:19

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:18:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:53:58
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONE ANTAGONISTS AND RELATED AGENTS, ATC: OTHER HORMONE ANTAGONISTS AND RELATED AGENTS, PRODUCT: DEGARELIX ACETATE, PRODUCTSYNONYM: FIRMAGON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 06:38:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 06:38:52
Data point term sent to Coder	System	09 Mar 2021 00:54:10
User entered 'Degarelix (firmagon)'	Jiamin Li (b) (4)	09 Mar 2021 00:53:32

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:18:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:53:58
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'No (N)'	Jiamin Li (b) (4)	09 Mar 2021 00:53:32

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:18:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:53:58
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Prostate cancer'	Jiamin Li (b) (4)	09 Mar 2021 00:53:32

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:18:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:53:58
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '120'	Jiamin Li (b) (4)	09 Mar 2021 00:53:32

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:18:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:53:58
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'mg (mg)'	Jiamin Li (b) (4)	09 Mar 2021 00:53:32

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:18:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:53:58
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4)	09 Mar 2021 00:53:32

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:18:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:53:58
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'once (ONCE)'	Jiamin Li (b) (4)	09 Mar 2021 00:53:32

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:18:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:53:58
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4)	09 Mar 2021 00:53:32

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:18:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:53:58
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Intramuscular (INTRAMUSCULAR)'	Jiamin Li (b) (4)	09 Mar 2021 00:53:32

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:18:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:53:58
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4)	09 Mar 2021 00:53:32

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:53:58
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '05 Feb 2021'	Jiamin Li (b) (4)	09 Mar 2021 00:53:32

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:18:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:53:58
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '0'	Jiamin Li (b) (4)	09 Mar 2021 00:53:32

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:18:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:53:58
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'No (N)'	Jiamin Li (b) (4)	09 Mar 2021 00:53:32

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:18:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:53:58
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '05 Feb 2021'	Jiamin Li (b) (4)	09 Mar 2021 00:53:32

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:18:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:53:58
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'No (N)'	Jiamin Li (b) (4)	09 Mar 2021 00:53:32

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:18:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:53:58
User entered empty.	System	09 Mar 2021 00:53:32

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:18:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:53:58
User entered empty.	System	09 Mar 2021 00:53:32

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:18:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:53:58
User entered empty.	System	09 Mar 2021 00:53:32

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:54:01
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
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, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 00:58:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 00:58:45
Data point term sent to Coder User entered 'Motrin'	System Jiamin Li (b) (4) (b) (4)	09 Mar 2021 00:58:11 09 Mar 2021 00:57:20

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:54:01
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'No (N)'	Jiamin Li (b) (4)	09 Mar 2021 00:57:20

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:54:01
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Fever'	Jiamin Li (b) (4)	09 Mar 2021 00:57:20

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:54:01
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '200'	Jiamin Li (b) (4)	09 Mar 2021 00:57:20

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:54:01
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'mg (mg)'	Jiamin Li (b) (4)	09 Mar 2021 00:57:20

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:54:01
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4)	09 Mar 2021 00:57:20

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:54:01
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'as needed (PRN)'	Jiamin Li (b) (4)	09 Mar 2021 00:57:20

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:54:01
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4)	09 Mar 2021 00:57:20

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:54:01
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'Oral (ORAL)'	Jiamin Li (b) (4)	09 Mar 2021 00:57:20

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:52

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:54:01
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4)	09 Mar 2021 00:57:20

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:54:01
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '09 Feb 2021'	Jiamin Li (b) (4)	09 Mar 2021 00:57:20

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:54:01
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '0'	Jiamin Li (b) (4)	09 Mar 2021 00:57:20

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:54:01
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'No (N)'	Jiamin Li (b) (4)	09 Mar 2021 00:57:20

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:54:01
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered '09 Feb 2021'	Jiamin Li (b) (4)	09 Mar 2021 00:57:20

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:54:01
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
User entered 'No (N)'	Jiamin Li (b) (4)	09 Mar 2021 00:57:20

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:54:01
User entered empty.	System	09 Mar 2021 00:57:20

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:54:01
User entered empty.	System	09 Mar 2021 00:57:20

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:54:01
User entered empty.	System	09 Mar 2021 00:57:20

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:18:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONES AND RELATED AGENTS, ATC: GONADOTROPIN RELEASING HORMONE ANALOGUES, PRODUCT: LEUPRORELIN ACETATE, PRODUCTSYNONYM: ELIGARD - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 08:50:48
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 Apr 2021 08:50:48
Data point term sent to Coder	System	13 Apr 2021 16:32:21
User entered 'Leuprolide acetate (eligard) injection'	Jiamin Li (b) (4) (b) (4)	13 Apr 2021 16:32:18

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:18:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	13 Apr 2021 16:32:18

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:18:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'Prostate cancer'	Jiamin Li (b) (4) (b) (4)	13 Apr 2021 16:32:18

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:18:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered '22.5'	Jiamin Li (b) (4) (b) (4)	13 Apr 2021 16:32:18

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:18:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	13 Apr 2021 16:32:18

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:18:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4) (b) (4)	13 Apr 2021 16:32:18

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:18:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'once (ONCE)'	Jiamin Li (b) (4) (b) (4)	13 Apr 2021 16:32:18

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:18:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4) (b) (4)	13 Apr 2021 16:32:18

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:18:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jiamin Li (b) (4) (b) (4)	13 Apr 2021 16:32:18

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:18:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4) (b) (4)	13 Apr 2021 16:32:18

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:18:52

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered '05 Mar 2021'	Jiamin Li (b) (4) (b) (4)	13 Apr 2021 16:32:18

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:18:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered '0'	Jiamin Li (b) (4) (b) (4)	13 Apr 2021 16:32:18

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:18:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	13 Apr 2021 16:32:18

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:18:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered empty.	Jiamin Li (b) (4) (b) (4)	13 Apr 2021 16:32:18

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:18:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:26:05
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	13 Apr 2021 16:32:18

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:18:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 16:32:18

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:18:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 16:32:18

US3702040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:18:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 16:32:18

US3702040

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:18:52

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:26:05
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4)	10 Apr 2021 12:27:51
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	10 Apr 2021 12:27:03
	(b) (4)	
User entered 'No (N)'	Jiamin Li (b) (4)	17 Mar 2021 20:03:07
	(b) (4)	

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'USA-US133-2021-MRNA-1273-P301000004'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'Yes (Y)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'No (N)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'Yes (Y)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'No (N)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'No (N)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'No (N)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'No (N)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'Kristen'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'Marks'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered '525 East 68th Street'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'New York'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'NY'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered '10065'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:21:15
User entered 'US'	System	09 Mar 2021 14:49:58

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	14 Apr 2021 17:40:31
User entered '2'	System	31 Mar 2021 14:21:27
User entered '1'	System	09 Mar 2021 14:49:58

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'USA-US133-2021-MRNA-1273-P301000004'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'Yes (Y)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'No (N)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'Yes (Y)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'No (N)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'No (N)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'No (N)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'No (N)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'Kristen'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'Marks'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered '525 East 68th Street'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'New York'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'NY'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered '10065'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:21:15
User entered 'US'	System	09 Mar 2021 14:49:58

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	14 Apr 2021 17:40:31
User entered '2'	System	31 Mar 2021 14:21:27
User entered '1'	System	09 Mar 2021 14:49:58

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:18:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
User entered '09/Mar/2021 08:49'	System	09 Mar 2021 14:49:58

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:18:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:21:15
User entered 'I'	(b) (4), (b) (6)	09 Mar 2021 14:49:58

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'USA-US133-2021-MRNA-1273-P301000004'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'Yes (Y)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'No (N)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'Yes (Y)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'No (N)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'No (N)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'No (N)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'No (N)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'Kristen'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'Marks'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered '525 East 68th Street'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'New York'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'NY'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered '10065'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:21:15
User entered 'US'	System	09 Mar 2021 14:49:58

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	14 Apr 2021 17:40:31
User entered '2'	System	31 Mar 2021 14:21:27
User entered '1'	System	09 Mar 2021 14:49:58

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:18:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
User entered '31/Mar/2021 10:21'	System	31 Mar 2021 14:21:27

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:18:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 17:40:17
User entered 'I'	(b) (4), (b) (6)	31 Mar 2021 14:21:27

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'USA-US133-2021-MRNA-1273-P301000004'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'Yes (Y)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'No (N)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'Yes (Y)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'No (N)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'No (N)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'No (N)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'No (N)'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'Kristen'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'Marks'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered '525 East 68th Street'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'New York'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered 'NY'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:49:52
User entered '10065'	System	09 Mar 2021 14:49:32

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:21:15
User entered 'US'	System	09 Mar 2021 14:49:58

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:18:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	14 Apr 2021 17:40:31
User entered '2'	System	31 Mar 2021 14:21:27
User entered '1'	System	09 Mar 2021 14:49:58

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:18:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
User entered '14/Apr/2021 13:40'	System	14 Apr 2021 17:40:31

US3702040

Folder: SAE USA-US133-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:18:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:28:48
User entered 'I'	(b) (4), (b) (6)	14 Apr 2021 17:40:31