

US3702046 (Prod: Weill Cornell Chelsea - (CRS))

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:19:45

All time stamps listed in this document are displayed in GMT

US3702046

Form: Participant Creation

Data signed: (b) (4) 16 Apr 2021 13:35:12

Generated On: 10 Jun 2021 09:19:45

Participant ID

US3702046

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

US3702046

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 19:21:35

Generated On: 10 Jun 2021 09:19:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	SCRN

US3702046

Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 19:21:35

Generated On: 10 Jun 2021 09:19:45

Date of Birth (MMM yyyy)	(b) (6) 1970
Age	49
Age Units	YEARS
Age (Derived)	49
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	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

US3702046

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 19:21:35

Generated On: 10 Jun 2021 09:19:45

Date of Informed Consent (*dd MMM yyyy*) 23 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

US3702046

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 19:21:35

Generated On: 10 Jun 2021 09:19:45

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3702046

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 23 Feb 2021 19:21:35

Generated On: 10 Jun 2021 09:19:45

Were any significant conditions reported?

Yes ☒
No ☐

US3702046

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 23 Feb 2021 19:21:35

Generated On: 10 Jun 2021 09:19:45

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3702046

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Feb 2021 19:21:35

Generated On: 10 Jun 2021 09:19:45

Condition	MORBID OBESITY WITH BMI OF 40.0 - 44.9
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3702046

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 23 Feb 2021 19:21:35

Generated On: 10 Jun 2021 09:19:45

Condition	ACNE
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3702046

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 19:21:35

Generated On: 10 Jun 2021 09:19:45

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	25 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:29 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 09:29
Height (<i>xxx.x</i>)	180.7 cm
Weight (<i>xxx.x</i>)	144.3 kg
BMI (<i>xxx.x</i>)	44.19265 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	36.5 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	87 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3702046

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 19:21:35

Generated On: 10 Jun 2021 09:19:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 SEP 2020

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

US3702046

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 19:21:35

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 19:21:35

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	True
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	TAKES THE SUBWAY A FEW TIMES / WEEK

US3702046

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 19:21:45

Generated On: 10 Jun 2021 09:19:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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

US3702046

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 23 Feb 2021 19:21:45

Generated On: 10 Jun 2021 09:19:45

What was the date of randomization? (dd MMM yyyy) 25 SEP 2020

What was the participant's randomization number? 146789

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 ☒

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 19:21:45

Generated On: 10 Jun 2021 09:19:45

Height	180.7 cm
Weight	144.3 kg

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 19:21:45

Generated On: 10 Jun 2021 09:19:45

Height	180.7 cm
Weight	144.3 kg
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)	25 SEP 2020
Time of assessment (00:00-23:59)	09:29 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 09:29
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 19:21:45

Generated On: 10 Jun 2021 09:19:45

Height	180.7 cm
Weight	144.3 kg
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)	25 SEP 2020
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 11:30
Temperature (xxx.x)	36.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3702046

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 19:21:45

Generated On: 10 Jun 2021 09:19:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 SEP 2020

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

US3702046

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 19:21:35

Generated On: 10 Jun 2021 09:19:45

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) 25 SEP 2020

What was the treatment time? (00:00-23:59) 10:34 (24 HR)

Treatment Date and Time (derived) 25 SEP 2020 10:34

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

US3702046

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 19:21:35

Generated On: 10 Jun 2021 09:19:45

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

Collection date (dd MMM yyyy)	25 SEP 2020
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Collection time (00:00-23:59)	09:58 (24 HR)
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Collection date and time (derived)	25 SEP 2020 09:58
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US3702046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 19:21:35

Generated On: 10 Jun 2021 09:19:45

Collection date (dd MMM yyyy)			25 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:31	25 SEP 2020 10:31
Nasopharyngeal Swab 2	No		

US3702046

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:21:35

Generated On: 10 Jun 2021 09:19:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 11:37

PC Open Date & Time

25 SEP 2020 10:54

PC Close Date & Time

25 SEP 2020 13:24

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

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 98.3 °F

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

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

PC Time Stamp	25 SEP 2020 18:29
PC Open Date & Time	25 SEP 2020 14:19
PC Close Date & Time	26 SEP 2020 11:59

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:45

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

98.5 °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

26 SEP 2020 20:24

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:45

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

27 SEP 2020 19:31

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:45

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

98.8 °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

28 SEP 2020 23:46

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:45

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

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 19:50

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:45

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 19:29

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:45

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 17:56

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

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

25 SEP 2020 11:10

PC Open Date & Time

25 SEP 2020 10:54

PC Close Date & Time

25 SEP 2020 13:24

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

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

25 SEP 2020 18:29

PC Open Date & Time

25 SEP 2020 14:19

PC Close Date & Time

26 SEP 2020 11:59

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:45

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

26 SEP 2020 20:24

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:45

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

27 SEP 2020 19:32

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:45

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

28 SEP 2020 23:46

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:45

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

29 SEP 2020 19:50

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:45

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

30 SEP 2020 19:30

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:45

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

01 OCT 2020 17:56

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

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 ☐

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 11:38
PC Open Date & Time	25 SEP 2020 10:54
PC Close Date & Time	25 SEP 2020 13:24

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

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 ☐

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 18:30
PC Open Date & Time	25 SEP 2020 14:19
PC Close Date & Time	26 SEP 2020 11:59

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:45

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 ☒

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:45

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 20:25
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:45

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 ☒

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:45

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 19:32
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:45

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 ☒

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:45

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 23:46
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 2423

EAB) (1725)

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:45

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 19:50
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

52 of 2423

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:45

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 19:30
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 2423

EAB) (1725)

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:45

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 17:56
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3702046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 19:21:35

Generated On: 10 Jun 2021 09:19:45

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3702046

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:21:35

Generated On: 10 Jun 2021 09:19:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 19:21:35

Generated On: 10 Jun 2021 09:19:45

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 OCT 2020

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

Comments PARTICIPANT DID NOT PICK UP.

If Contact Not Made, please provide Comments

US3702046

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:21:35

Generated On: 10 Jun 2021 09:19:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 19:21:35

Generated On: 10 Jun 2021 09:19:45

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments PATIENT NOT ABLE TO TAKE
CALLS.

If Contact Not Made, please provide Comments

US3702046

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:21:35

Generated On: 10 Jun 2021 09:19:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 19:21:45

Generated On: 10 Jun 2021 09:19:45

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

Visit date (dd MMM yyyy)	23 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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US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 19:21:45

Generated On: 10 Jun 2021 09:19:45

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)	23 OCT 2020
Time of assessment (00:00-23:59)	09:18 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 09:18
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)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 19:21:45

Generated On: 10 Jun 2021 09:19:45

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)	23 OCT 2020
Time of assessment (00:00-23:59)	10:46 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 10:46
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG

US3702046

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 19:21:45

Generated On: 10 Jun 2021 09:19:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 OCT 2020

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

US3702046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 19:21:45

Generated On: 10 Jun 2021 09:19:45

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) 23 OCT 2020

What was the treatment time? (00:00-23:59) 10:08 (24 HR)

Treatment Date and Time (derived) 23 OCT 2020 10:08

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

What was the frequency of the study treatment dosing? ONCE

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

US3702046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 19:21:45

Generated On: 10 Jun 2021 09:19:45

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

Collection date (dd MMM yyyy)	23 OCT 2020
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Collection time (00:00-23:59)	09:39 (24 HR)
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Collection date and time (derived)	23 OCT 2020 09:39
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US3702046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 19:21:45

Generated On: 10 Jun 2021 09:19:45

Collection date (dd MMM yyyy)			23 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:06	23 OCT 2020 10:06
Nasopharyngeal Swab 2	No		

US3702046

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:21:45

Generated On: 10 Jun 2021 09:19:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

23 OCT 2020 10:45

PC Open Date & Time

23 OCT 2020 10:28

PC Close Date & Time

23 OCT 2020 12:58

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

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

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

23 OCT 2020 13:53

PC Close Date & Time

24 OCT 2020 11:59

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:45

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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

24 OCT 2020 12:39

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 OCT 2020 16:57

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 OCT 2020 12:57

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:45

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 OCT 2020 14:22

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 OCT 2020 13:34

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

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

23 OCT 2020 10:44

PC Open Date & Time

23 OCT 2020 10:28

PC Close Date & Time

23 OCT 2020 12:58

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

23 OCT 2020 13:53

PC Close Date & Time

24 OCT 2020 11:59

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

5

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 OCT 2020 12:40

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:45

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

25 OCT 2020 16:58

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:45

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

26 OCT 2020 12:57

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:45

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

27 OCT 2020 14:22

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:45

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

29 OCT 2020 13:34

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

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 ☐

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

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

No ☒

Yes ☐

PC Time stamp	23 OCT 2020 10:43
PC Open Date & Time	23 OCT 2020 10:28
PC Close Date & Time	23 OCT 2020 12:58

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

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 ☐

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

23 OCT 2020 13:53

PC Close Date & Time

24 OCT 2020 11:59

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:45

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 ☒

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:45

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 12:39
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:45

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 ☒

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:45

Yes <input type="checkbox"/>	
PC Time stamp	25 OCT 2020 16:58
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:45

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 ☒

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:45

Yes <input type="checkbox"/>	
PC Time stamp	26 OCT 2020 13:00
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:45

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 ☒

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:45

Yes <input type="checkbox"/>	
PC Time stamp	27 OCT 2020 14:22
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

98 of 2423

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:45

Yes ☐

PC Time stamp

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:45

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 ☒

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:45

Yes <input type="checkbox"/>	
PC Time stamp	29 OCT 2020 13:35
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3702046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 19:21:35

Generated On: 10 Jun 2021 09:19:45

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3702046

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:21:35

Generated On: 10 Jun 2021 09:19:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 19:21:35

Generated On: 10 Jun 2021 09:19:45

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 09 NOV 2020

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

Comments PARTICIPANT DID NOT PICK UP

If Contact Not Made, please provide Comments

US3702046

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:21:35

Generated On: 10 Jun 2021 09:19:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702046

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 19:21:35

Generated On: 10 Jun 2021 09:19:45

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 09 NOV 2020

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

Comments PARTICIPANT DID NOT PICK UP

If Contact Not Made, please provide Comments

US3702046

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:21:35

Generated On: 10 Jun 2021 09:19:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702046

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 19:21:45

Generated On: 10 Jun 2021 09:19:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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

US3702046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 19:21:45

Generated On: 10 Jun 2021 09:19:45

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 NOV 2020
Time of assessment (00:00-23:59)	10:00 (24 HR)
Vital Signs Date and Time (derived)	19 NOV 2020 10:00
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	INFORMATION NOT KNOWN
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3702046

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 19:21:45

Generated On: 10 Jun 2021 09:19:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 NOV 2020

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

US3702046

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 19:21:45

Generated On: 10 Jun 2021 09:19:45

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 NOV 2020

Collection time (00:00-23:59)

09:46 (24 HR)

Collection date and time (derived)

19 NOV 2020 09:46

US3702046

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:21:45

Generated On: 10 Jun 2021 09:19:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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 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"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Close Date & Time](#)

24 DEC 2020 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Close Date & Time](#)

31 DEC 2020 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 103

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

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

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

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

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

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

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 117

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

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

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

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

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

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

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

17 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

31 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 138

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

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

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

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

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

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

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 152

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

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

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

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

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

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

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 159

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

28 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 166

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

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

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

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

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

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

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 187

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

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

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

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

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

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

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

28 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 208

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 215

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

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

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

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

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 229

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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="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"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 JUN 2021 00:01
Patient Cloud Close Date & Time	24 JUN 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 JUL 2021 00:01
Patient Cloud Close Date & Time	29 JUL 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 327

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 SEP 2021 00:01
Patient Cloud Close Date & Time	16 SEP 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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 ☐ Yes ☐

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

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 DEC 2021 00:01
Patient Cloud Close Date & Time	09 DEC 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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="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"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 495

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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°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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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°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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 APR 2022 00:01
Patient Cloud Close Date & Time	28 APR 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 607

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

No ☐

Yes ☐

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

Fever (Temperature \geq 100.4°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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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°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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 642

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 712

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

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

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

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

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

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

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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 ☐

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

[Patient Cloud Close Date & Time](#)

24 NOV 2022 23:59

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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"/>

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2022 23:59

US3702046

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 20:56:59

Generated On: 10 Jun 2021 09:19:45

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3702046

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:56:58

Generated On: 10 Jun 2021 09:19:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702046

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 13:35:12

Generated On: 10 Jun 2021 09:19:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3702046

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 13:35:12

Generated On: 10 Jun 2021 09:19:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702046

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 13:35:12

Generated On: 10 Jun 2021 09:19:45

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3702046

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 13:35:12

Generated On: 10 Jun 2021 09:19:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702046

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 13:35:12

Generated On: 10 Jun 2021 09:19:45

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 MAR 2021

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

Comments PARTICIPANT DID NOT PICK UP
AFTER MULTIPLE ATTEMPTS.

If Contact Not Made, please provide Comments

US3702046

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 13:35:12

Generated On: 10 Jun 2021 09:19:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3702046

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:45

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3702046

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

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)	

US3702046

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:19:45

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.

US3702046

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:45

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/>

US3702046

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:45

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3702046

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:19:45

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"/>

US3702046

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:19:45

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3702046

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

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 13:35:12

Generated On: 10 Jun 2021 09:19:45

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

Visit date (dd MMM yyyy)	22 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3702046

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 13:35:12

Generated On: 10 Jun 2021 09:19:45

Date of updated informed consent (dd MMM yyyy) 22 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 22 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3702046

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 13:35:12

Generated On: 10 Jun 2021 09:19:45

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

Collection date (dd MMM yyyy)	22 JAN 2021
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Collection time (00:00-23:59)	12:35 (24 HR)
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Collection date and time (derived)	22 JAN 2021 12:35
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US3702046

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 13:35:12

Generated On: 10 Jun 2021 09:19:45

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 JAN 2021

Collection time (00:00 - 23:59)

12:31

Collection Date and Time (derived)

22 JAN 2021 12:31

US3702046

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 19:29:30

Generated On: 10 Jun 2021 09:19:45

AEID	USA-US133-2021-MRNA-1273-P30 1000005
Adverse event	BIPOLAR DISORDER WITH PSYCHOSIS
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 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	09 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	09 MAR 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	346 of 2423

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 19:29:30

Generated On: 10 Jun 2021 09:19:45

Number of Days in ICU	1
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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	

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 19:29:30

Generated On: 10 Jun 2021 09:19:45

PT IS A 50 YEAR OLD MALE(IP
ARM, LAST VISIT OL3 VISIT
22JAN2021). ON 26FEB21 PT
PRESENTED TO THE
PSYCHIATRIC EVALUATION
PROGRAM-JACOBI HOSPITAL
WITH THE FOLLOWING:
BIZARRE BEHAVIOR,
SELECTIVE MUTISM,
AGITATION, STRIPPING OF
CLOTHING.
PMH: BIPOLAR DISORDER,
HYPERTENSION, DIABETES
MELLITUS, SLEEP APNEA. PT
RAN HEADFIRST INTO A WALL;
REQUIRING RESTRAINT. HEAD
CTS AND CXR NEG.
TRANSFERRED TO
PSYCHIATRY. STARTED ON
LITHIUM, HALOPERIDOL,
ATIVAN. DENIED ETOH/ILLCIT
SUBSTANCE USE. AFEBRILE.
NEG COVID SWAB. WBC
ELEVATED.
DAY 4, THE PT C/O NEW ONSET
SOB. TACHYCARDIA AND LE
EDEMA NOTED.
CT-ANGIOGRAM SHOWED
MULTIPLE
SEGMENTAL/SUBSEGMENTAL
PULMONARY EMBOLI, LEFT
WORSE THAN RIGHT.
ANTICOAGULATION WITH
LOVENOX 120MG Q12H

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 19:29:30

Generated On: 10 Jun 2021 09:19:45

STARTED.
DAY 5 MS ALTERED. ABG
DONE--PAO2 = 77. ATIVAN AND
LITHIUM WERE D/C'D. MENTAL
STATUS IMPROVED. URINARY
RETENTION REQ. FOLEY CATH.
TEE REVEALED NORMAL LVEF
AND NO RV STRAIN. DUPLEX
STUDY WAS ALSO NEGATIVE
FOR DVT.
HYPERCOAGULABILITY
WORKUP NEG. LEVENOX
CHANGED TO ABIXABAN 5MG
BID DAY 8. PT FOUND
UNRESPONSIVE ON MORNING
OF DAY 9. NOTED TO BE
CONFUSED, DIAPHORETIC,
TREMULOUS. LEFT
CONJUNCTIVITIS, PURULENT
DISCHARGE, LESIONS NOTED.
CXR NL, URCX NEG. ABIXABAN
CHANGED TO LOVENOX.
ON DAY 11 COVID SWAB NEG
DAY 12 EPISODE OF RECTAL
BLEEDING WITH CLOTS.
FEBRILE TO 102.6F.
TACHYCARDIC. BP NL, OS SAT
95%. FOUND SHORTLY
THEREAFTER TO BE
UNRESPONSIVE.
RESUSCITATION
UNSUCCESSFUL. TIME OF
DEATH 1:59 PM.

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)	1

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 19:29:30

Generated On: 10 Jun 2021 09:19:45

AEID	
Adverse event	LUMBAR BACK PAIN
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)	27 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	09 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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	

PRODUCTION RELEASE (v12.003
EAB) (1725)

350 of 2423

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 19:29:30

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 May 2021 19:29:30

Generated On: 10 Jun 2021 09:19:45

AEID	USA-US133-2021-MRNA-1273-P30 1000005
Adverse event	PULMONARY EMBOLISM
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	09 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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	True
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	09 MAR 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

352 of 2423

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 May 2021 19:29:30

Generated On: 10 Jun 2021 09:19:45

Number of Days in ICU	1
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input checked="" type="radio"/> Not Recovered/Not Resolved <input 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	

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 May 2021 19:29:30

Generated On: 10 Jun 2021 09:19:45

PT IS A 50 YEAR OLD MALE(IP
ARM, LAST VISIT OL3 VISIT
22JAN2021). ON 26FEB21 PT
PRESENTED TO THE
PSYCHIATRIC EVALUATION
PROGRAM-JACOBI HOSPITAL
WITH THE FOLLOWING:
BIZARRE BEHAVIOR,
SELECTIVE MUTISM,
AGITATION, STRIPPING OF
CLOTHING.
PMH: BIPOLAR DISORDER,
HYPERTENSION, DIABETES
MELLITUS, SLEEP APNEA. PT
RAN HEADFIRST INTO A WALL;
REQUIRING RESTRAINT. HEAD
CTS AND CXR NEG.
TRANSFERRED TO
PSYCHIATRY. STARTED ON
LITHIUM, HALOPERIDOL,
ATIVAN. DENIED ETOH/ILLCIT
SUBSTANCE USE. AFEBRILE.
NEG COVID SWAB. WBC
ELEVATED.
DAY 4, THE PT C/O NEW ONSET
SOB. TACHYCARDIA AND LE
EDEMA NOTED.
CT-ANGIOGRAM SHOWED
MULTIPLE
SEGMENTAL/SUBSEGMENTAL
PULMONARY EMBOLI, LEFT
WORSE THAN RIGHT.
ANTICOAGULATION WITH
LOVENOX 120MG Q12H

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 May 2021 19:29:30

Generated On: 10 Jun 2021 09:19:45

STARTED.
DAY 5 MS ALTERED. ABG
DONE--PAO2 = 77. ATIVAN AND
LITHIUM WERE D/C'D. MENTAL
STATUS IMPROVED. URINARY
RETENTION REQ. FOLEY CATH.
TEE REVEALED NORMAL LVEF
AND NO RV STRAIN. DUPLEX
STUDY WAS ALSO NEGATIVE
FOR DVT.
HYPERCOAGULABILITY
WORKUP NEG. LEVENOX
CHANGED TO ABIXABAN 5MG
BID DAY 8. PT FOUND
UNRESPONSIVE ON MORNING
OF DAY 9. NOTED TO BE
CONFUSED, DIAPHORETIC,
TREMULOUS. LEFT
CONJUNCTIVITIS, PURULENT
DISCHARGE, LESIONS NOTED.
CXR NL, URCX NEG. ABIXABAN
CHANGED TO LOVENOX.
ON DAY 11 COVID SWAB NEG
DAY 12 EPISODE OF RECTAL
BLEEDING WITH CLOTS.
FEBRILE TO 102.6F.
TACHYCARDIC. BP NL, OS SAT
95%. FOUND SHORTLY
THEREAFTER TO BE
UNRESPONSIVE.
RESUSCITATION
UNSUCCESSFUL. TIME OF
DEATH 1:59 PM.

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)	1

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 03 May 2021 19:29:30

Generated On: 10 Jun 2021 09:19:45

AEID	
Adverse event	CONJUNCTIVITIS
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)	06 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	09 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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	

PRODUCTION RELEASE (v12.003
EAB) (1725)

356 of 2423

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 03 May 2021 19:29:30

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 03 May 2021 19:29:30

Generated On: 10 Jun 2021 09:19:45

AEID	
Adverse event	UPPER EXTREMITY TREMOR
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)	06 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	09 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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	

PRODUCTION RELEASE (v12.003
EAB) (1725)

358 of 2423

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 03 May 2021 19:29:30

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 03 May 2021 19:29:30

Generated On: 10 Jun 2021 09:19:45

AEID	USA-US133-2021-MRNA-1273-P30 1000005
Adverse event	GASTROINTESTINAL BLEED
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)	09 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	09 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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	True
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	09 MAR 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

360 of 2423

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 03 May 2021 19:29:30

Generated On: 10 Jun 2021 09:19:45

Number of Days in ICU	1
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input checked="" type="radio"/> Not Recovered/Not Resolved <input 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)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	1

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 03 May 2021 19:29:30

Generated On: 10 Jun 2021 09:19:45

AEID	
Adverse event	FEVER
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)	09 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	09 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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	

PRODUCTION RELEASE (v12.003
EAB) (1725)

362 of 2423

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 03 May 2021 19:29:30

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 03 May 2021 19:29:30

Generated On: 10 Jun 2021 09:19:45

AEID USA-US133-2021-MRNA-1273-P30
1000005

Adverse event PULSELESS ELECTRICAL
ACTIVITY

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 MAR 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 MAR 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 True

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 ☐
No ☐
Unknown ☐

PRODUCTION RELEASE (v12.003 364 of 2423
EAB) (1725)

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 03 May 2021 19:29:30

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 03 May 2021 19:29:30

Generated On: 10 Jun 2021 09:19:45

PT IS A 50 YEAR OLD MALE(IP
ARM, LAST VISIT OL3 VISIT
22JAN2021). ON 26FEB21 PT
PRESENTED TO THE
PSYCHIATRIC EVALUATION
PROGRAM-JACOBI HOSPITAL
WITH THE FOLLOWING:
BIZARRE BEHAVIOR,
SELECTIVE MUTISM,
AGITATION, STRIPPING OF
CLOTHING.
PMH: BIPOLAR DISORDER,
HYPERTENSION, DIABETES
MELLITUS, SLEEP APNEA. PT
RAN HEADFIRST INTO A WALL;
REQUIRING RESTRAINT. HEAD
CTS AND CXR NEG.
TRANSFERRED TO
PSYCHIATRY. STARTED ON
LITHIUM, HALOPERIDOL,
ATIVAN. DENIED ETOH/ILLCIT
SUBSTANCE USE. AFEBRILE.
NEG COVID SWAB. WBC
ELEVATED.
DAY 4, THE PT C/O NEW ONSET
SOB. TACHYCARDIA AND LE
EDEMA NOTED.
CT-ANGIOGRAM SHOWED
MULTIPLE
SEGMENTAL/SUBSEGMENTAL
PULMONARY EMBOLI, LEFT
WORSE THAN RIGHT.
ANTICOAGULATION WITH
LOVENOX 120MG Q12H

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 03 May 2021 19:29:30

Generated On: 10 Jun 2021 09:19:45

STARTED.
DAY 5 MS ALTERED. ABG
DONE--PAO2 = 77. ATIVAN AND
LITHIUM WERE D/C'D. MENTAL
STATUS IMPROVED. URINARY
RETENTION REQ. FOLEY CATH.
TEE REVEALED NORMAL LVEF
AND NO RV STRAIN. DUPLEX
STUDY WAS ALSO NEGATIVE
FOR DVT.
HYPERCOAGULABILITY
WORKUP NEG. LEVENOX
CHANGED TO ABIXABAN 5MG
BID DAY 8. PT FOUND
UNRESPONSIVE ON MORNING
OF DAY 9. NOTED TO BE
CONFUSED, DIAPHORETIC,
TREMULOUS. LEFT
CONJUNCTIVITIS, PURULENT
DISCHARGE, LESIONS NOTED.
CXR NL, URCX NEG. ABIXABAN
CHANGED TO LOVENOX.
ON DAY 11 COVID SWAB NEG
DAY 12 EPISODE OF RECTAL
BLEEDING WITH CLOTS.
FEBRILE TO 102.6F.
TACHYCARDIC. BP NL, OS SAT
95%. FOUND SHORTLY
THEREAFTER TO BE
UNRESPONSIVE.
RESUSCITATION
UNSUCCESSFUL. TIME OF
DEATH 1:59 PM.

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)	

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Apr 2021 13:35:12

Generated On: 10 Jun 2021 09:19:45

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

Yes ☒

No ☐

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

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

369 of 2423

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	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)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 28 SEP 2020		
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"/>

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HIGH BLOOD PRESSURE
DISORDER

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

371 of 2423

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	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) _____		
Start date completely unknown		True
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"/>

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication IBUPROFEN

Prophylaxis Yes ☒
No ☐

Indication HEADACHE PREVENTION

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

373 of 2423

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	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)		24 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 OCT 2020
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"/>

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication MULTIVITAMIN (BRAND UNKNOWN)

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH SUPPLEMENT

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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)

375 of 2423

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication INFLUENZA VACCINATION

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

377 of 2423

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	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)	UN SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		UN SEP 2020
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"/>

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication LORAZEPAM

Prophylaxis Yes ☐
No ☒

Indication AGITATION (RELATED TO
BIPOLAR DISORDER WITH
PSYCHOSIS)

Dose per administration 2

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

TWICE

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

379 of 2423

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	Intraocular	<input type="radio"/>
	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)	26 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)		28 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"/>

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication HALOPERIDOL

Prophylaxis Yes ☐
No ☒

Indication PSYCHOSIS (RELATED TO
BIPOLAR DISORDER)

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

381 of 2423

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	Intraocular	<input type="radio"/>
	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)	26 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)		26 FEB 2021
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"/>

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication HUMALOG

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS

Dose per administration 0-6

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

383 of 2423

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 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)		08 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication ENOXAPARIN

Prophylaxis Yes ☐
No ☒

Indication PULMONARY EMBOLISM

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

385 of 2423

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		04 MAR 2021
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"/>

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

387 of 2423

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 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 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

389 of 2423

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 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 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

391 of 2423

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 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) 27 FEB 2021		
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"/>

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication LUMBAR BACK PAIN

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

393 of 2423

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	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)	28 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 MAR 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"/>

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication LORAZEPAM

Prophylaxis Yes ☐
No ☒

Indication AGITATION (RELATED TO
BIPOLAR DISORDER WITH
PSYCHOSIS)

Dose per administration 2

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)

395 of 2423

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	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)	01 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 MAR 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"/>

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication HALOPERIDOL

Prophylaxis Yes ☐
No ☒

Indication BIPOLAR DISORDER WITH
PSYCHOSIS

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

EVERY 12 HOURS

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

397 of 2423

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	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)	01 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 MAR 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"/>

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

399 of 2423

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	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 MAR 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 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication LOHEXOL

Prophylaxis Yes ☐
No ☒

Indication CONTRAST FOR CT

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

401 of 2423

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" 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)	01 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)		01 MAR 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"/>

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication LITHIUM

Prophylaxis Yes ☐
No ☒

Indication BIPOLAR DISORDER WITH
PSYCHOSIS

Dose per administration 300

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)

403 of 2423

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	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)	01 MAR 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 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication TRAZODONE

Prophylaxis Yes ☐
No ☒

Indication BIPOLAR DISORDER WITH
PSYCHOSIS

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

405 of 2423

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	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)	01 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication ENOXAPARIN

Prophylaxis Yes ☐
No ☒

Indication PULMONARY EMBOLISM

Dose per administration 135

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

EVERY 12 HOURS

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

PRODUCTION RELEASE (v12.003

407 of 2423

EAB) (1725)

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 MAR 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"/>

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication PULMONARY EMBOLISM

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

409 of 2423

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	05 MAR 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 MAR 2021
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"/>

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication LORAZEPAM

Prophylaxis Yes ☐
No ☒

Indication AGITATION (RELATED TO
BIPOLAR DISORDER WITH
PSYCHOSIS)

Dose per administration 1

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

EVERY 8 HOURS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

411 of 2423

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" 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)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 MAR 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"/>

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐
No ☒

Indication HYDRATION

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 ☐

PRODUCTION RELEASE (v12.003

413 of 2423

EAB) (1725)

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" 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)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	06 MAR 2021	
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"/>	

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication ERYTHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication CONJUNCTIVITIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

415 of 2423

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	09 MAR 2021	
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"/>

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication HALOPERIDOL

Prophylaxis Yes ☐
No ☒

Indication PSYCHOSIS (RELATED TO
BIPOLAR DISORDER)

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

EVERY 12 HOURS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

417 of 2423

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	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 checked="" 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)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 MAR 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"/>

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication LORAZEPAM

Prophylaxis Yes ☐
No ☒

Indication AGITATION (RELATED TO
BIPOLAR DISORDER WITH
PSYCHOSIS)

Dose per administration 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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

419 of 2423

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	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 checked="" 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)	08 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication BENZTROPINE

Prophylaxis Yes ☐
No ☒

Indication UPPER EXTREMITY TREMOR

Dose per administration 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

EVERY 12 HOURS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

421 of 2423

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	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)		06 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		08 MAR 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"/>

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication DEXROSE 5% - LACTATED RINGERS

Prophylaxis Yes ☐
No ☒

Indication HYDRATION

Dose per administration 1

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)

423 of 2423

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	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 checked="" 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)	08 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 MAR 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"/>

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication FEVER

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

425 of 2423

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 03 May 2021 19:29:31

Generated On: 10 Jun 2021 09:19:45

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" 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)	09 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	09 MAR 2021	
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"/>

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 03 May 2021 19:29:32

Generated On: 10 Jun 2021 09:19:45

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 03 May 2021 19:29:32

Generated On: 10 Jun 2021 09:19:45

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
01 MAR 2021	CT SCAN	Adverse Event	
26 FEB 2021	HEAD CTS AND CXR	Adverse Event	
01 MAR 2021	CT ANGIOGRAM	Adverse Event	
05 MAR 2021	TRANSESOPHAGEAL ECHOCARDIOGRAM	Adverse Event	
05 MAR 2021	DUPLEX STUDY	Adverse Event	
08 MAR 2021	CHEST X-RAY	Adverse Event	
08 MAR 2021	URINE CULTURE	Adverse Event	

US3702046

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:19:45

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

US3702046

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:19:45

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 ☐

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 03 May 2021 19:29:32

Generated On: 10 Jun 2021 09:19:45

SAEID	USA-US133-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	2

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 03 May 2021 19:29:32

Generated On: 10 Jun 2021 09:19:45

SAEID	USA-US133-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	2
Date of submission (Pre-filled from custom function)	30/APR/2021 14:14
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

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 03 May 2021 19:29:32

Generated On: 10 Jun 2021 09:19:45

SAEID	USA-US133-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	2
Date of submission (Pre-filled from custom function)	03/MAY/2021 10:38
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

US3702046 (Prod: Weill Cornell Chelsea - (CRS))

US3702046

Form: Participant Creation

Generated On: 10 Jun 2021 09:19:45

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'US3702046'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Sep 2020 12:54:25

US3702046

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:19:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Mia Crowley (b) (4)	25 Sep 2020 14:37:50

US3702046

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:19:45

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '23 Sep 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Oct 2020 20:34:18
User entered '25 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Sep 2020 12:54:26

US3702046

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:19:45

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 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Home (Home)' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Oct 2020 20:34:18
User entered 'Clinic (Clinic)'	Mia Crowley (b) (4)	25 Sep 2020 14:37:50

US3702046

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:19:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered 'SCRN'	System	25 Sep 2020 14:37:50

US3702046

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered (b) (6) 1970'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Sep 2020 12:54:27

US3702046

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:45

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '49'	Jiamin Li (b) (4)	29 Sep 2020 04:48:58

US3702046

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:45

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered 'YEARS'	System	29 Sep 2020 04:48:58

US3702046

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:45

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered '49'	System	25 Sep 2020 14:38:08

US3702046

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:45

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Male (M)'	Jiamin Li (b) (4)	29 Sep 2020 04:48:58

US3702046

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:45

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Jiamin Li (b) (4)	29 Sep 2020 04:48:58

US3702046

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:45

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	29 Sep 2020 04:48:58

US3702046

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:45

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'I'	Jiamin Li (b) (4)	29 Sep 2020 04:48:58

US3702046

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:45

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	29 Sep 2020 04:48:58

US3702046

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:45

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	29 Sep 2020 04:48:58

US3702046

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:45

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	29 Sep 2020 04:48:58

US3702046

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:45

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	29 Sep 2020 04:48:58

US3702046

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:45

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	29 Sep 2020 04:48:58

US3702046

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:45

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	29 Sep 2020 04:48:58

US3702046

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:45

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	29 Sep 2020 04:48:58

US3702046

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:19:45

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '23 Sep 2020'	Mia Crowley (b) (4)	25 Sep 2020 14:38:08

US3702046

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered 'Sep 2020'	System	25 Sep 2020 14:38:08

US3702046

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered '2020'	System	25 Sep 2020 14:38:08

US3702046

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:19:45

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 14:38:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 14:38:15
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	Mia Crowley (b) (4)	25 Sep 2020 14:38:15
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 14:38:08
User entered empty.	Mia Crowley (b) (4)	25 Sep 2020 14:38:08

US3702046

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Mia Crowley (b) (4)	25 Sep 2020 14:38:08

US3702046

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Mia Crowley (b) (4)	25 Sep 2020 14:38:08

US3702046

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:19:45

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Mia Crowley (b) (4)	25 Sep 2020 14:38:08

US3702046

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:19:45

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Mia Crowley (b) (4)	25 Sep 2020 14:38:08

US3702046

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:19:45

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	25 Sep 2020 12:54:26

US3702046

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:19:45

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered 'I'	System	25 Sep 2020 14:38:08

US3702046

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Mia Crowley (b) (4)	25 Sep 2020 14:37:33

US3702046

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:19:45

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Oct 2020 20:35:43

US3702046

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:19:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 20:37:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 20:37:29
Data point term sent to Coder	System	12 Oct 2020 20:36:11
User entered 'Hypertension'	Jiamin Li (b) (4)	12 Oct 2020 20:36:04

US3702046

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'un UNK 2018'	Jiamin Li (b) (4)	12 Oct 2020 20:36:04

US3702046

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	12 Oct 2020 20:36:04

US3702046

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:19:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Oct 2020 20:36:04

US3702046

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 20:36:04

US3702046

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:19:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	12 Oct 2020 20:36:04

US3702046

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered 'Jan 2018'	System	12 Oct 2020 20:36:04

US3702046

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered '2018'	System	12 Oct 2020 20:36:04

US3702046

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered empty.	System	12 Oct 2020 20:36:04

US3702046

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered empty.	System	12 Oct 2020 20:36:04

US3702046

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:19:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
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: Morbid obesity - version MedDRA\23.0.	Coder Import (b) (4)	13 Oct 2020 00:15:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	13 Oct 2020 00:15:25
Data point term sent to Coder	System	12 Oct 2020 20:37:12
User entered 'Morbid obesity with BMI of 40.0 - 44.9'	Jiamin Li (b) (4)	12 Oct 2020 20:36:15

US3702046

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 20:36:15

US3702046

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'I'	Jiamin Li (b) (4)	12 Oct 2020 20:36:15

US3702046

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:19:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Oct 2020 20:36:15

US3702046

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 20:36:15

US3702046

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:19:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	12 Oct 2020 20:36:15

US3702046

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered empty.	System	12 Oct 2020 20:36:15

US3702046

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered empty.	System	12 Oct 2020 20:36:15

US3702046

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered empty.	System	12 Oct 2020 20:36:15

US3702046

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered empty.	System	12 Oct 2020 20:36:15

US3702046

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:19:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Acnes, PT: Acne, LLT: Acne - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 20:38:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 20:38:23
Data point term sent to Coder	System	12 Oct 2020 20:37:12
User entered 'Acne'	Jiamin Li (b) (4)	12 Oct 2020 20:36:23

US3702046

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 20:36:23

US3702046

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'I'	Jiamin Li (b) (4)	12 Oct 2020 20:36:23

US3702046

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:19:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Oct 2020 20:36:23

US3702046

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 20:36:23

US3702046

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:19:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	12 Oct 2020 20:36:23

US3702046

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered empty.	System	12 Oct 2020 20:36:23

US3702046

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered empty.	System	12 Oct 2020 20:36:23

US3702046

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered empty.	System	12 Oct 2020 20:36:23

US3702046

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered empty.	System	12 Oct 2020 20:36:23

US3702046

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
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)	23 Nov 2020 01:35:47
User entered 'No (N)'	Jiamin Li (b) (4)	12 Oct 2020 20:35:29

US3702046

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	30 Dec 2020 19:12:58
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered with 'Screen and entry done on separate days.' (Site from System).	Jiamin Li (b) (4)	07 Dec 2020 19:43:03
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	07 Dec 2020 19:42:05
User entered '25 Sep 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	07 Dec 2020 19:42:05
User entered '23 Sep 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	23 Nov 2020 01:35:47
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 20:35:29

US3702046

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '09:29' reason for change: Data Entry Error	Jiamin Li (b) (4)	07 Dec 2020 19:42:05
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 07:04:42
Query 'Data is required. Please provide.' answered with 'Vital signs not assessed. Answer but be marked as yes or else system query generates if rest of info is marked as ND (as requested per CDM)' (Site from System).	Jiamin Li (b) (4)	23 Nov 2020 01:35:51
User opened query 'Data is required. Please provide.' System (Site from System).		23 Nov 2020 01:35:47
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 20:35:29

US3702046

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered '25 Sep 2020 09:29'	System	07 Dec 2020 19:42:05
User entered empty.	System	12 Oct 2020 20:35:29

US3702046

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '180.7' cm reason for change: Data Entry Error	Jiamin Li (b) (4)	07 Dec 2020 19:42:05
User closed query 'per CDM: please use drop down menu to enter ND if height/weight were not taken during this visit, otherwise please clarify' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 07:04:44
Query 'per CDM: please use drop down menu to enter ND if height/weight were not taken during this visit, otherwise please clarify' answered with 'Vital signs not assessed. Answer but be marked as yes or else system query generates if rest of info is marked as ND (as requested per CDM)' (Site from DM).	Jiamin Li (b) (4)	23 Nov 2020 01:35:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Jiamin Li (b) (4)	23 Nov 2020 01:35:47
User opened query 'per CDM: please use drop down menu to enter ND if height/weight were not taken during this visit, otherwise please clarify' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 17:55:07
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 20:35:29
DataPoint set to visible.	System	25 Sep 2020 14:38:08

US3702046

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '144.3' kg reason for change: Data Entry Error	Jiamin Li (b) (4)	07 Dec 2020 19:42:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Jiamin Li (b) (4)	23 Nov 2020 01:35:47
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 20:35:29
DataPoint set to visible.	System	25 Sep 2020 14:38:08

US3702046

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered '44.19265'	System	07 Dec 2020 19:42:05
User entered empty.	System	12 Oct 2020 20:35:29
DataPoint set to visible.	System	25 Sep 2020 14:38:08

US3702046

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered 'kg/m2'	System	07 Dec 2020 19:42:05
User entered empty.	System	12 Oct 2020 20:35:29
DataPoint set to visible.	System	25 Sep 2020 14:38:08

US3702046

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '36.5' C reason for change: Data Entry Error	Jiamin Li (b) (4)	07 Dec 2020 19:42:05
User closed query 'per CDM: if vital signs were not taken, please use drop down menu to input ND for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 07:04:47
Query 'per CDM: if vital signs were not taken, please use drop down menu to input ND for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP' answered with 'Vital signs not assessed. Answer but be marked as yes or else system query generates if rest of info is marked as ND (as requested per CDM)' (Site from DM).	Jiamin Li (b) (4)	23 Nov 2020 01:35:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Jiamin Li (b) (4)	23 Nov 2020 01:35:47
User opened query 'per CDM: if vital signs were not taken, please use drop down menu to input ND for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 14:55:12
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 20:35:29

US3702046

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Other (Other)' reason for change: Data Entry Error	Jiamin Li (b) (4)	07 Dec 2020 19:42:05
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 20:35:29

US3702046

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Temporal' reason for change: Data Entry Error	Jiamin Li (b) (4)	07 Dec 2020 19:42:05
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 20:35:29

US3702046

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '87' reason for change: Data Entry Error	Jiamin Li (b) (4)	07 Dec 2020 19:42:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Jiamin Li (b) (4)	23 Nov 2020 01:35:47
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 20:35:29

US3702046

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered 'bpm'	System	23 Nov 2020 01:35:47
User entered empty.	System	12 Oct 2020 20:35:29

US3702046

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '16' reason for change: Data Entry Error	Jiamin Li (b) (4)	07 Dec 2020 19:42:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Jiamin Li (b) (4)	23 Nov 2020 01:35:47
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 20:35:29

US3702046

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered 'breaths/min'	System	23 Nov 2020 01:35:47
User entered empty.	System	12 Oct 2020 20:35:29

US3702046

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '128' reason for change: Data Entry Error	Jiamin Li (b) (4)	07 Dec 2020 19:42:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Jiamin Li (b) (4)	23 Nov 2020 01:35:47
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 20:35:29

US3702046

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered 'mmHg'	System	23 Nov 2020 01:35:47
User entered empty.	System	12 Oct 2020 20:35:29

US3702046

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '89' reason for change: Data Entry Error	Jiamin Li (b) (4)	07 Dec 2020 19:42:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Jiamin Li (b) (4)	23 Nov 2020 01:35:47
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 20:35:29

US3702046

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered 'mmHg'	System	23 Nov 2020 01:35:47
User entered empty.	System	12 Oct 2020 20:35:29

US3702046

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42

US3702046

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42

US3702046

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:19:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
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)	07 Dec 2020 19:43:11
User entered 'No (N)'	Jiamin Li (b) (4)	12 Oct 2020 20:35:34

US3702046

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:19:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '25 Sep 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	07 Dec 2020 19:43:11
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 20:35:34

US3702046

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:45

[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 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	12 Oct 2020 20:35:23

US3702046

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:45

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 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	12 Oct 2020 20:35:23

US3702046

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:45

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 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Oct 2020 20:35:23

US3702046

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:45

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 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	12 Oct 2020 20:35:23

US3702046

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:45

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 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	12 Oct 2020 20:35:23

US3702046

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:45

[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 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	12 Oct 2020 20:35:23

US3702046

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:45

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 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	12 Oct 2020 20:35:23

US3702046

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:45

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 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	12 Oct 2020 20:35:23

US3702046

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:45

[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 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	12 Oct 2020 20:35:23

US3702046

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:45

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 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	12 Oct 2020 20:35:23

US3702046

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:45

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 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	12 Oct 2020 20:35:23

US3702046

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:45

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	12 Oct 2020 20:35:23

US3702046

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:45

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 20:35:23

US3702046

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:45

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	12 Oct 2020 20:35:23

US3702046

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	12 Oct 2020 20:35:23

US3702046

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:45

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 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'I'	Jiamin Li (b) (4)	12 Oct 2020 20:35:23

US3702046

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:45

[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 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	12 Oct 2020 20:35:23

US3702046

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:45

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 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	12 Oct 2020 20:35:23

US3702046

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '0'	Jiamin Li (b) (4)	12 Oct 2020 20:35:23

US3702046

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:45

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'I'	Jiamin Li (b) (4)	12 Oct 2020 20:35:23

US3702046

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:45

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Takes the subway a few times / week'	Jiamin Li (b) (4)	12 Oct 2020 20:35:23

US3702046

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:19:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Yes (Y)'	Mia Crowley (b) (4)	25 Sep 2020 14:37:21

US3702046

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '25 Sep 2020'	Mia Crowley (b) (4)	25 Sep 2020 14:37:21

US3702046

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:19:45

[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 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Clinic (Clinic)'	Mia Crowley (b) (4)	25 Sep 2020 14:37:21

US3702046

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:19:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User entered 'VISIT1'	System	25 Sep 2020 14:37:21

US3702046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '25 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Sep 2020 13:44:14

US3702046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '146789'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Sep 2020 13:44:14

US3702046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Sep 2020 13:44:14

US3702046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:19:45

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 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'No (N)'	Jiamin Li (b) (4)	29 Sep 2020 04:49:27

US3702046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:19:45

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 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'No (N)'	Jiamin Li (b) (4)	29 Sep 2020 04:49:27

US3702046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Yes (Y)'	Jiamin Li (b) (4)	29 Sep 2020 04:49:27

US3702046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'No (N)'	Jiamin Li (b) (4)	29 Sep 2020 04:49:27

US3702046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:19:45

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'No (N)'	Jiamin Li (b) (4)	29 Sep 2020 04:49:27

US3702046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:19:45

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'No (N)'	Jiamin Li (b) (4)	29 Sep 2020 04:49:27
DataPoint set to visible.	System	25 Sep 2020 14:38:15

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:19:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '180.7' cm	Jiamin Li (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:19:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '144.3' kg	Jiamin Li (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:19:45

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '180.7' cm	Jiamin Li (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:19:45

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '144.3' kg	Jiamin Li (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User accepted default value 'Pre-Dose (PREDOSE)'	Jiamin Li (b) (4) (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '25 Sep 2020'	Jiamin Li (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Oct 2020 20:40:42
Query 'Data is required. Please provide.' answered by System data change (Site from System).		12 Oct 2020 20:40:42
User entered '09:29' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Oct 2020 20:40:42
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Oct 2020 20:40:33
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User entered '25 Sep 2020 09:29'	System	12 Oct 2020 20:40:42
User entered empty.	System	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '36.5' C	Jiamin Li (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Other (Other)'	Jiamin Li (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Temporal'	Jiamin Li (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '87'	Jiamin Li (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User entered 'bpm'	System	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '16'	Jiamin Li (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User entered 'breaths/min'	System	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '128'	Jiamin Li (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User entered 'mmHg'	System	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '89'	Jiamin Li (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User entered 'mmHg'	System	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:19:45

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '180.7' cm	Jiamin Li (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:19:45

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '144.3' kg	Jiamin Li (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User accepted default value 'Post-Dose (POSTDOSE)'	Jiamin Li (b) (4) (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '25 Sep 2020'	Jiamin Li (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '11:30'	Jiamin Li (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User entered '25 Sep 2020 11:30'	System	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '36.2' C	Jiamin Li (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Oral (Oral)'	Jiamin Li (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '74'	Jiamin Li (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User entered 'bpm'	System	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '16'	Jiamin Li (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User entered 'breaths/min'	System	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '118'	Jiamin Li (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User entered 'mmHg'	System	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '87'	Jiamin Li (b) (4)	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User entered 'mmHg'	System	12 Oct 2020 20:40:33

US3702046

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:19:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Oct 2020 20:39:30

US3702046

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:19:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '25 Sep 2020'	Jiamin Li (b) (4)	12 Oct 2020 20:39:30

US3702046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:19:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Mia Crowley (b) (4)	25 Sep 2020 14:42:50

US3702046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:19:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Mia Crowley (b) (4)	25 Sep 2020 14:42:50

US3702046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:19:45

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 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Mia Crowley (b) (4)	25 Sep 2020 14:42:50

US3702046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:19:45

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User entered 'MRNA-1273 OR PLACEBO'	System	25 Sep 2020 14:42:50

US3702046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:19:45

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '25 Sep 2020'	Mia Crowley (b) (4)	25 Sep 2020 14:42:50

US3702046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '10:34'	Mia Crowley (b) (4)	25 Sep 2020 14:42:50

US3702046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User entered '25 Sep 2020 10:34'	System	25 Sep 2020 14:42:50

US3702046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:19:45

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Left Arm (LEFT ARM)'	Mia Crowley (b) (4)	25 Sep 2020 14:42:50

US3702046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:19:45

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User entered 'ONCE'	System	25 Sep 2020 14:42:50

US3702046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:19:45

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User entered 'INTRAMUSCULAR'	System	25 Sep 2020 14:42:50

US3702046

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	29 Sep 2020 04:49:50

US3702046

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '25 Sep 2020'	Jiamin Li (b) (4)	29 Sep 2020 04:49:50

US3702046

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:45

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '09:58'	Jiamin Li (b) (4)	29 Sep 2020 04:49:50

US3702046

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User entered '25 Sep 2020 09:58'	System	29 Sep 2020 04:49:50

US3702046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '25 Sep 2020'	Jiamin Li (b) (4)	12 Oct 2020 20:41:08

US3702046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:19:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jiamin Li (b) (4) (b) (4)	12 Oct 2020 20:41:08

US3702046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:19:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Oct 2020 20:41:08

US3702046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:19:45

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '10:31'	Jiamin Li (b) (4)	12 Oct 2020 20:41:08

US3702046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User entered '25 Sep 2020 10:31'	System	12 Oct 2020 20:41:08

US3702046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:19:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jiamin Li (b) (4) (b) (4)	12 Oct 2020 20:41:08

US3702046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:19:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'No (N)'	Jiamin Li (b) (4)	12 Oct 2020 20:41:08

US3702046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:19:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 20:41:08

US3702046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User entered empty.	System	12 Oct 2020 20:41:08

US3702046

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:19:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Genessi Rodriguez (b) (4)	07 Oct 2020 19:10:35

US3702046

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:19:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User entered 'I'	System	07 Oct 2020 19:10:35

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	25 Sep 2020 14:42:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T11:37:12', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '83363a27-42ea-41ca-af2c-c675482f0683'	System	25 Sep 2020 15:38:07
User entered 'Yes (Y)'	System	25 Sep 2020 15:38:07

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T11:37:37', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '83363a27-42ea-41ca-af2c-c675482f0683' User entered '97.2'	System	25 Sep 2020 15:38:07
	System	25 Sep 2020 15:38:07

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T11:37:43', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '83363a27-42ea-41ca-af2c-c675482f0683'	System	25 Sep 2020 15:38:07
User entered 'No (N)'	System	25 Sep 2020 15:38:07

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T11:37:49', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '83363a27-42ea-41ca-af2c-c675482f0683'	System	25 Sep 2020 15:38:07
User entered '25 Sep 2020 11:37'	System	25 Sep 2020 15:38:07

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '25 Sep 2020 10:54'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '25 Sep 2020 13:24'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	25 Sep 2020 14:42:50
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T18:26:57', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'b8bca0af-938b-4bf3-8e13-c4c0f9a05808'	System	25 Sep 2020 22:29:19
User entered 'Yes (Y)'	System	25 Sep 2020 22:29:19

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T18:29:05', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'b8bca0af-938b-4bf3-8e13-c4c0f9a05808' User entered '98.3'	System	25 Sep 2020 22:29:19
	System	25 Sep 2020 22:29:19

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T18:29:10', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'b8bca0af-938b-4bf3-8e13-c4c0f9a05808'	System	25 Sep 2020 22:29:19
User entered 'No (N)'	System	25 Sep 2020 22:29:19

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T18:29:15', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'b8bca0af-938b-4bf3-8e13-c4c0f9a05808'	System	25 Sep 2020 22:29:19
User entered '25 Sep 2020 18:29'	System	25 Sep 2020 22:29:19

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '25 Sep 2020 14:19'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	25 Sep 2020 14:42:50
User entered 'Day 2'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:45

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-26T20:23:59', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'e11f3fe8-a9dd-44d6-83ae-a9a16375f2c1'	System	27 Sep 2020 00:24:24
User entered 'Yes (Y)'	System	27 Sep 2020 00:24:24

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-26T20:24:06', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'e11f3fe8-a9dd-44d6-83ae-a9a16375f2c1'	System	27 Sep 2020 00:24:24
User entered '98.5'	System	27 Sep 2020 00:24:24

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-26T20:24:13', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'e11f3fe8-a9dd-44d6-83ae-a9a16375f2c1'	System	27 Sep 2020 00:24:24
User entered 'No (N)'	System	27 Sep 2020 00:24:24

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-26T20:24:17', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'e11f3fe8-a9dd-44d6-83ae-a9a16375f2c1'	System	27 Sep 2020 00:24:24
User entered '26 Sep 2020 20:24'	System	27 Sep 2020 00:24:24

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	25 Sep 2020 14:42:50
User entered 'Day 3'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:45

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-27T19:31:35', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '3e7a612f-163c-46b8-be25-3efa81b4795d'	System	27 Sep 2020 23:31:53
User entered 'Yes (Y)'	System	27 Sep 2020 23:31:53

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-27T19:31:41', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '3e7a612f-163c-46b8-be25-3efa81b4795d' User entered '98.5'	System	27 Sep 2020 23:31:53

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-27T19:31:45', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '3e7a612f-163c-46b8-be25-3efa81b4795d'	System	27 Sep 2020 23:31:53
User entered 'No (N)'	System	27 Sep 2020 23:31:53

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-27T19:31:48', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '3e7a612f-163c-46b8-be25-3efa81b4795d'	System	27 Sep 2020 23:31:53
User entered '27 Sep 2020 19:31'	System	27 Sep 2020 23:31:53

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	25 Sep 2020 14:42:50
User entered 'Day 4'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:45

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-28T23:45:48', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd711caf7-5101-4305-a8d6-82ef89e9c726'	System	29 Sep 2020 03:46:05
User entered 'Yes (Y)'	System	29 Sep 2020 03:46:05

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-28T23:45:54', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd711caf7-5101-4305-a8d6-82ef89e9c726'	System	29 Sep 2020 03:46:05
User entered '98.8'	System	29 Sep 2020 03:46:05

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-28T23:45:58', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd711caf7-5101-4305-a8d6-82ef89e9c726'	System	29 Sep 2020 03:46:05
User entered 'No (N)'	System	29 Sep 2020 03:46:05

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-28T23:46:01', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd711caf7-5101-4305-a8d6-82ef89e9c726'	System	29 Sep 2020 03:46:05
User entered '28 Sep 2020 23:46'	System	29 Sep 2020 03:46:05

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	25 Sep 2020 14:42:50
User entered 'Day 5'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-29T19:49:39', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'b21b307e-84ca-4ae4-864a-9b3eb3ff86ec'	System	29 Sep 2020 23:50:05
User entered 'Yes (Y)'	System	29 Sep 2020 23:50:05

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-29T19:49:52', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'b21b307e-84ca-4ae4-864a-9b3eb3ff86ec'	System	29 Sep 2020 23:50:05
User entered '99.2'	System	29 Sep 2020 23:50:05

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-29T19:49:57', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'b21b307e-84ca-4ae4-864a-9b3eb3ff86ec'	System	29 Sep 2020 23:50:05
User entered 'No (N)'	System	29 Sep 2020 23:50:05

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-29T19:50:01', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'b21b307e-84ca-4ae4-864a-9b3eb3ff86ec'	System	29 Sep 2020 23:50:05
User entered '29 Sep 2020 19:50'	System	29 Sep 2020 23:50:05

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	25 Sep 2020 14:42:50
User entered 'Day 6'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-30T19:29:32', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd8f4d4e0-e23f-45e1-8de7-0989b96da69f'	System	30 Sep 2020 23:30:04
User entered 'Yes (Y)'	System	30 Sep 2020 23:30:04

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-30T19:29:46', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd8f4d4e0-e23f-45e1-8de7-0989b96da69f'	System	30 Sep 2020 23:30:04
User entered '96.8'	System	30 Sep 2020 23:30:04

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-30T19:29:49', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd8f4d4e0-e23f-45e1-8de7-0989b96da69f'	System	30 Sep 2020 23:30:04
User entered 'No (N)'	System	30 Sep 2020 23:30:04

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-30T19:29:54', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd8f4d4e0-e23f-45e1-8de7-0989b96da69f'	System	30 Sep 2020 23:30:04
User entered '30 Sep 2020 19:29'	System	30 Sep 2020 23:30:04

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	25 Sep 2020 14:42:50
User entered 'Day 7'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-01T17:55:50', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '8ff840f8-38ff-49d7-9575-0779f23c2e21'	System	01 Oct 2020 21:56:06
User entered 'Yes (Y)'	System	01 Oct 2020 21:56:06

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-01T17:55:55', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '8ff840f8-38ff-49d7-9575-0779f23c2e21'	System	01 Oct 2020 21:56:06
User entered '98.2'	System	01 Oct 2020 21:56:06

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-01T17:55:59', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '8ff840f8-38ff-49d7-9575-0779f23c2e21'	System	01 Oct 2020 21:56:06
User entered 'No (N)'	System	01 Oct 2020 21:56:06

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-01T17:56:02', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '8ff840f8-38ff-49d7-9575-0779f23c2e21'	System	01 Oct 2020 21:56:06
User entered '01 Oct 2020 17:56'	System	01 Oct 2020 21:56:06

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	25 Sep 2020 14:42:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T11:09:48', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '79e19002-31d8-4d44-b898-21672719ef54'	System	25 Sep 2020 15:10:51
User entered 'None (1)'	System	25 Sep 2020 15:10:51

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T11:10:01', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '79e19002-31d8-4d44-b898-21672719ef54'	System	25 Sep 2020 15:10:51
User entered 'No (N)'	System	25 Sep 2020 15:10:51

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T11:10:04', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '79e19002-31d8-4d44-b898-21672719ef54'	System	25 Sep 2020 15:10:51
User entered 'No (N)'	System	25 Sep 2020 15:10:51

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T11:10:09', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '79e19002-31d8-4d44-b898-21672719ef54'	System	25 Sep 2020 15:10:51
User entered 'None (1)'	System	25 Sep 2020 15:10:51

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T11:10:30', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '79e19002-31d8-4d44-b898-21672719ef54'	System	25 Sep 2020 15:10:51
User entered '25 Sep 2020 11:10'	System	25 Sep 2020 15:10:51

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '25 Sep 2020 10:54'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '25 Sep 2020 13:24'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	25 Sep 2020 14:42:50
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T18:29:26', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '93121376-d3ba-48cd-9c65-20e7bbf00fc5'	System	25 Sep 2020 22:29:52
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 22:29:52

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T18:29:29', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '93121376-d3ba-48cd-9c65-20e7bbf00fc5'	System	25 Sep 2020 22:29:52
User entered 'No (N)'	System	25 Sep 2020 22:29:52

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T18:29:35', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '93121376-d3ba-48cd-9c65-20e7bbf00fc5'	System	25 Sep 2020 22:29:52
User entered 'No (N)'	System	25 Sep 2020 22:29:52

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T18:29:43', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '93121376-d3ba-48cd-9c65-20e7bbf00fc5'	System	25 Sep 2020 22:29:52
User entered 'None (1)'	System	25 Sep 2020 22:29:52

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T18:29:46', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '93121376-d3ba-48cd-9c65-20e7bbf00fc5'	System	25 Sep 2020 22:29:52
User entered '25 Sep 2020 18:29'	System	25 Sep 2020 22:29:52

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '25 Sep 2020 14:19'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	25 Sep 2020 14:42:50
User entered 'Day 2'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-26T20:24:28', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'ae41e3ff-31b0-4fa1-a168-7b8fe7899bf7'	System	27 Sep 2020 00:24:51
User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 00:24:51

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-26T20:24:33', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'ae41e3ff-31b0-4fa1-a168-7b8fe7899bf7'	System	27 Sep 2020 00:24:51
User entered 'No (N)'	System	27 Sep 2020 00:24:51

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-26T20:24:39', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'ae41e3ff-31b0-4fa1-a168-7b8fe7899bf7'	System	27 Sep 2020 00:24:51
User entered 'No (N)'	System	27 Sep 2020 00:24:51

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-26T20:24:42', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'ae41e3ff-31b0-4fa1-a168-7b8fe7899bf7'	System	27 Sep 2020 00:24:51
User entered 'None (1)'	System	27 Sep 2020 00:24:51

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-26T20:24:45', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'ae41e3ff-31b0-4fa1-a168-7b8fe7899bf7'	System	27 Sep 2020 00:24:51
User entered '26 Sep 2020 20:24'	System	27 Sep 2020 00:24:51

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	25 Sep 2020 14:42:50
User entered 'Day 3'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-27T19:31:58', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '3db4ef20-6eb8-4b11-b58a-13a569f7e8d8'	System	27 Sep 2020 23:32:17
User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 23:32:17

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-27T19:32:02', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '3db4ef20-6eb8-4b11-b58a-13a569f7e8d8'	System	27 Sep 2020 23:32:17
User entered 'No (N)'	System	27 Sep 2020 23:32:17

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-27T19:32:04', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '3db4ef20-6eb8-4b11-b58a-13a569f7e8d8'	System	27 Sep 2020 23:32:17
User entered 'No (N)'	System	27 Sep 2020 23:32:17

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-27T19:32:07', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '3db4ef20-6eb8-4b11-b58a-13a569f7e8d8'	System	27 Sep 2020 23:32:17
User entered 'None (1)'	System	27 Sep 2020 23:32:17

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-27T19:32:10', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '3db4ef20-6eb8-4b11-b58a-13a569f7e8d8'	System	27 Sep 2020 23:32:17
User entered '27 Sep 2020 19:32'	System	27 Sep 2020 23:32:17

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	25 Sep 2020 14:42:50
User entered 'Day 4'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-28T23:46:08', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '6947ea18-70a6-4600-a413-995b2b2eed70'	System	29 Sep 2020 03:46:23
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 03:46:23

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-28T23:46:11', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '6947ea18-70a6-4600-a413-995b2b2eed70'	System	29 Sep 2020 03:46:23
User entered 'No (N)'	System	29 Sep 2020 03:46:23

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-28T23:46:12', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '6947ea18-70a6-4600-a413-995b2b2eed70'	System	29 Sep 2020 03:46:23
User entered 'No (N)'	System	29 Sep 2020 03:46:23

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-28T23:46:14', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '6947ea18-70a6-4600-a413-995b2b2eed70'	System	29 Sep 2020 03:46:23
User entered 'None (1)'	System	29 Sep 2020 03:46:23

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-28T23:46:17', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '6947ea18-70a6-4600-a413-995b2b2eed70'	System	29 Sep 2020 03:46:23
User entered '28 Sep 2020 23:46'	System	29 Sep 2020 03:46:23

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	25 Sep 2020 14:42:50
User entered 'Day 5'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-29T19:50:11', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'ffd36d5e-a5af-464a-a0dc-02f1615592db'	System	29 Sep 2020 23:50:26
User entered 'None (1)'	System	29 Sep 2020 23:50:26

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-29T19:50:14', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'ffd36d5e-a5af-464a-a0dc-02f1615592db'	System	29 Sep 2020 23:50:26
User entered 'No (N)'	System	29 Sep 2020 23:50:26

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-29T19:50:17', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'ffd36d5e-a5af-464a-a0dc-02f1615592db'	System	29 Sep 2020 23:50:26
User entered 'No (N)'	System	29 Sep 2020 23:50:26

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-29T19:50:19', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'ffd36d5e-a5af-464a-a0dc-02f1615592db'	System	29 Sep 2020 23:50:26
User entered 'None (1)'	System	29 Sep 2020 23:50:26

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-29T19:50:22', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'ffd36d5e-a5af-464a-a0dc-02f1615592db'	System	29 Sep 2020 23:50:26
User entered '29 Sep 2020 19:50'	System	29 Sep 2020 23:50:26

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	25 Sep 2020 14:42:50
User entered 'Day 6'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-30T19:30:03', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd2c84611-4789-4afe-b37f-acabd62555cd'	System	30 Sep 2020 23:30:24
User entered 'None (1)'	System	30 Sep 2020 23:30:24

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-30T19:30:10', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd2c84611-4789-4afe-b37f-acabd62555cd'	System	30 Sep 2020 23:30:24
User entered 'No (N)'	System	30 Sep 2020 23:30:24

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-30T19:30:14', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd2c84611-4789-4afe-b37f-acabd62555cd'	System	30 Sep 2020 23:30:24
User entered 'No (N)'	System	30 Sep 2020 23:30:24

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-30T19:30:17', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd2c84611-4789-4afe-b37f-acabd62555cd'	System	30 Sep 2020 23:30:24
User entered 'None (1)'	System	30 Sep 2020 23:30:24

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-30T19:30:20', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd2c84611-4789-4afe-b37f-acabd62555cd'	System	30 Sep 2020 23:30:24
User entered '30 Sep 2020 19:30'	System	30 Sep 2020 23:30:24

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	25 Sep 2020 14:42:50
User entered 'Day 7'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-01T17:56:09', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '6b42f4c3-6cc4-458a-92db-7e6248432f47'	System	01 Oct 2020 21:56:24
User entered 'None (1)'	System	01 Oct 2020 21:56:24

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-01T17:56:11', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '6b42f4c3-6cc4-458a-92db-7e6248432f47'	System	01 Oct 2020 21:56:24
User entered 'No (N)'	System	01 Oct 2020 21:56:24

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-01T17:56:13', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '6b42f4c3-6cc4-458a-92db-7e6248432f47'	System	01 Oct 2020 21:56:24
User entered 'No (N)'	System	01 Oct 2020 21:56:24

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-01T17:56:16', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '6b42f4c3-6cc4-458a-92db-7e6248432f47'	System	01 Oct 2020 21:56:24
User entered 'None (1)'	System	01 Oct 2020 21:56:24

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-01T17:56:19', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '6b42f4c3-6cc4-458a-92db-7e6248432f47'	System	01 Oct 2020 21:56:24
User entered '01 Oct 2020 17:56'	System	01 Oct 2020 21:56:24

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	25 Sep 2020 14:42:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T11:37:58', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '7ef033f5-458c-4456-b2cb-399ed6520d11'	System	25 Sep 2020 15:38:36
User entered 'None (0)'	System	25 Sep 2020 15:38:36

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T11:38:01', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '7ef033f5-458c-4456-b2cb-399ed6520d11'	System	25 Sep 2020 15:38:36
User entered 'None (0)'	System	25 Sep 2020 15:38:36

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T11:38:04', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '7ef033f5-458c-4456-b2cb-399ed6520d11'	System	25 Sep 2020 15:38:36
User entered 'None (0)'	System	25 Sep 2020 15:38:36

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T11:38:07', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '7ef033f5-458c-4456-b2cb-399ed6520d11'	System	25 Sep 2020 15:38:36
User entered 'None (0)'	System	25 Sep 2020 15:38:36

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T11:38:09', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '7ef033f5-458c-4456-b2cb-399ed6520d11'	System	25 Sep 2020 15:38:36
User entered 'None (0)'	System	25 Sep 2020 15:38:36

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T11:38:12', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '7ef033f5-458c-4456-b2cb-399ed6520d11'	System	25 Sep 2020 15:38:36
User entered 'None (0)'	System	25 Sep 2020 15:38:36

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T11:38:26', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '7ef033f5-458c-4456-b2cb-399ed6520d11'	System	25 Sep 2020 15:38:36
User entered 'No (N)'	System	25 Sep 2020 15:38:36

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T11:38:30', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '7ef033f5-458c-4456-b2cb-399ed6520d11'	System	25 Sep 2020 15:38:36
User entered '25 Sep 2020 11:38'	System	25 Sep 2020 15:38:36

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '25 Sep 2020 10:54'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '25 Sep 2020 13:24'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	25 Sep 2020 14:42:50
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T18:29:54', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '6dea0836-146a-4cb5-be39-99fded2246aa'	System	27 Sep 2020 00:23:55
User entered 'None (0)'	System	27 Sep 2020 00:23:55

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T18:29:55', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '6dea0836-146a-4cb5-be39-99fded2246aa'	System	27 Sep 2020 00:23:55
User entered 'None (0)'	System	27 Sep 2020 00:23:55

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T18:29:57', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '6dea0836-146a-4cb5-be39-99fded2246aa'	System	27 Sep 2020 00:23:55
User entered 'None (0)'	System	27 Sep 2020 00:23:55

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T18:29:59', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '6dea0836-146a-4cb5-be39-99fded2246aa'	System	27 Sep 2020 00:23:55
User entered 'None (0)'	System	27 Sep 2020 00:23:55

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T18:30:02', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '6dea0836-146a-4cb5-be39-99fded2246aa'	System	27 Sep 2020 00:23:55
User entered 'None (0)'	System	27 Sep 2020 00:23:55

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T18:30:04', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '6dea0836-146a-4cb5-be39-99fded2246aa'	System	27 Sep 2020 00:23:55
User entered 'None (0)'	System	27 Sep 2020 00:23:55

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T18:30:12', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '6dea0836-146a-4cb5-be39-99fded2246aa'	System	27 Sep 2020 00:23:55
User entered 'No (N)'	System	27 Sep 2020 00:23:55

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-25T18:30:15', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '6dea0836-146a-4cb5-be39-99fded2246aa'	System	27 Sep 2020 00:23:55
User entered '25 Sep 2020 18:30'	System	27 Sep 2020 00:23:55

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '25 Sep 2020 14:19'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	25 Sep 2020 14:42:50
User entered 'Day 2'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-26T20:24:50', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '918772e6-19cb-4dec-8cde-6d1b896743c2'	System	27 Sep 2020 00:25:18
User entered 'None (0)'	System	27 Sep 2020 00:25:18

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-26T20:24:52', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '918772e6-19cb-4dec-8cde-6d1b896743c2'	System	27 Sep 2020 00:25:18
User entered 'None (0)'	System	27 Sep 2020 00:25:18

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-26T20:24:54', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '918772e6-19cb-4dec-8cde-6d1b896743c2'	System	27 Sep 2020 00:25:18
User entered 'None (0)'	System	27 Sep 2020 00:25:18

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-26T20:24:57', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '918772e6-19cb-4dec-8cde-6d1b896743c2'	System	27 Sep 2020 00:25:18
User entered 'None (0)'	System	27 Sep 2020 00:25:18

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-26T20:24:59', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '918772e6-19cb-4dec-8cde-6d1b896743c2'	System	27 Sep 2020 00:25:18
User entered 'None (0)'	System	27 Sep 2020 00:25:18

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-26T20:25:01', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '918772e6-19cb-4dec-8cde-6d1b896743c2'	System	27 Sep 2020 00:25:18
User entered 'None (0)'	System	27 Sep 2020 00:25:18

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-26T20:25:08', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '918772e6-19cb-4dec-8cde-6d1b896743c2'	System	27 Sep 2020 00:25:18
User entered 'No (N)'	System	27 Sep 2020 00:25:18

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-26T20:25:11', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '918772e6-19cb-4dec-8cde-6d1b896743c2'	System	27 Sep 2020 00:25:18
User entered '26 Sep 2020 20:25'	System	27 Sep 2020 00:25:18

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	25 Sep 2020 14:42:50
User entered 'Day 3'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-27T19:32:17', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'f00aeff4-3d43-4b20-8e09-2388869380df' User entered 'None (0)'	System	27 Sep 2020 23:32:37

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-27T19:32:19', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'f00aeff4-3d43-4b20-8e09-2388869380df' User entered 'None (0)'	System	27 Sep 2020 23:32:37

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-27T19:32:21', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'f00aeff4-3d43-4b20-8e09-2388869380df'	System	27 Sep 2020 23:32:37
User entered 'None (0)'	System	27 Sep 2020 23:32:37

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-27T19:32:23', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'f00aeff4-3d43-4b20-8e09-2388869380df'	System	27 Sep 2020 23:32:37
User entered 'None (0)'	System	27 Sep 2020 23:32:37

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-27T19:32:25', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'f00aeff4-3d43-4b20-8e09-2388869380df' User entered 'None (0)'	System	27 Sep 2020 23:32:37

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-27T19:32:26', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'f00aeff4-3d43-4b20-8e09-2388869380df'	System	27 Sep 2020 23:32:37
User entered 'None (0)'	System	27 Sep 2020 23:32:37

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-27T19:32:29', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'f00aeff4-3d43-4b20-8e09-2388869380df'	System	27 Sep 2020 23:32:37
User entered 'No (N)'	System	27 Sep 2020 23:32:37

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-27T19:32:32', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'f00aeff4-3d43-4b20-8e09-2388869380df' User entered '27 Sep 2020 19:32'	System	27 Sep 2020 23:32:37

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	25 Sep 2020 14:42:50
User entered 'Day 4'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-28T23:46:23', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '03f383e5-5c8b-4324-9b17-757131cf1dbf'	System	29 Sep 2020 03:46:39
User entered 'No interference with activity (1)'	System	29 Sep 2020 03:46:39

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-28T23:46:25', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '03f383e5-5c8b-4324-9b17-757131cf1dbf'	System	29 Sep 2020 03:46:39
User entered 'None (0)'	System	29 Sep 2020 03:46:39

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-28T23:46:27', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '03f383e5-5c8b-4324-9b17-757131cf1dbf'	System	29 Sep 2020 03:46:39
User entered 'None (0)'	System	29 Sep 2020 03:46:39

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-28T23:46:28', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '03f383e5-5c8b-4324-9b17-757131cf1dbf'	System	29 Sep 2020 03:46:39
User entered 'None (0)'	System	29 Sep 2020 03:46:39

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-28T23:46:29', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '03f383e5-5c8b-4324-9b17-757131cf1dbf'	System	29 Sep 2020 03:46:39
User entered 'None (0)'	System	29 Sep 2020 03:46:39

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-28T23:46:31', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '03f383e5-5c8b-4324-9b17-757131cf1dbf'	System	29 Sep 2020 03:46:39
User entered 'None (0)'	System	29 Sep 2020 03:46:39

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-28T23:46:33', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '03f383e5-5c8b-4324-9b17-757131cf1dbf'	System	29 Sep 2020 03:46:39
User entered 'No (N)'	System	29 Sep 2020 03:46:39

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-28T23:46:35', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '03f383e5-5c8b-4324-9b17-757131cf1dbf'	System	29 Sep 2020 03:46:39
User entered '28 Sep 2020 23:46'	System	29 Sep 2020 03:46:39

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	25 Sep 2020 14:42:50
User entered 'Day 5'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-29T19:50:28', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'e2b020bf-4aaa-488f-b472-550717e6f782'	System	29 Sep 2020 23:50:44
User entered 'None (0)'	System	29 Sep 2020 23:50:44

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-29T19:50:30', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'e2b020bf-4aaa-488f-b472-550717e6f782'	System	29 Sep 2020 23:50:44
User entered 'None (0)'	System	29 Sep 2020 23:50:44

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-29T19:50:32', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'e2b020bf-4aaa-488f-b472-550717e6f782'	System	29 Sep 2020 23:50:44
User entered 'None (0)'	System	29 Sep 2020 23:50:44

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-29T19:50:34', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'e2b020bf-4aaa-488f-b472-550717e6f782'	System	29 Sep 2020 23:50:44
User entered 'None (0)'	System	29 Sep 2020 23:50:44

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-29T19:50:35', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'e2b020bf-4aaa-488f-b472-550717e6f782'	System	29 Sep 2020 23:50:44
User entered 'None (0)'	System	29 Sep 2020 23:50:44

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-29T19:50:38', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'e2b020bf-4aaa-488f-b472-550717e6f782'	System	29 Sep 2020 23:50:44
User entered 'None (0)'	System	29 Sep 2020 23:50:44

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-29T19:50:40', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'e2b020bf-4aaa-488f-b472-550717e6f782'	System	29 Sep 2020 23:50:44
User entered 'No (N)'	System	29 Sep 2020 23:50:44

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-29T19:50:42', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'e2b020bf-4aaa-488f-b472-550717e6f782'	System	29 Sep 2020 23:50:44
User entered '29 Sep 2020 19:50'	System	29 Sep 2020 23:50:44

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	25 Sep 2020 14:42:50
User entered 'Day 6'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-30T19:30:28', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '22687b18-c31e-4e68-bace-52e76dc6161b'	System	30 Sep 2020 23:30:55
User entered 'None (0)'	System	30 Sep 2020 23:30:55

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-30T19:30:30', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '22687b18-c31e-4e68-bace-52e76dc6161b'	System	30 Sep 2020 23:30:55
User entered 'None (0)'	System	30 Sep 2020 23:30:55

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-30T19:30:32', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '22687b18-c31e-4e68-bace-52e76dc6161b'	System	30 Sep 2020 23:30:55
User entered 'None (0)'	System	30 Sep 2020 23:30:55

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-30T19:30:35', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '22687b18-c31e-4e68-bace-52e76dc6161b'	System	30 Sep 2020 23:30:55
User entered 'None (0)'	System	30 Sep 2020 23:30:55

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-30T19:30:37', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '22687b18-c31e-4e68-bace-52e76dc6161b'	System	30 Sep 2020 23:30:55
User entered 'None (0)'	System	30 Sep 2020 23:30:55

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-30T19:30:41', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '22687b18-c31e-4e68-bace-52e76dc6161b'	System	30 Sep 2020 23:30:55
User entered 'None (0)'	System	30 Sep 2020 23:30:55

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-30T19:30:44', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '22687b18-c31e-4e68-bace-52e76dc6161b'	System	30 Sep 2020 23:30:55
User entered 'No (N)'	System	30 Sep 2020 23:30:55

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-09-30T19:30:49', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '22687b18-c31e-4e68-bace-52e76dc6161b'	System	30 Sep 2020 23:30:55
User entered '30 Sep 2020 19:30'	System	30 Sep 2020 23:30:55

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	25 Sep 2020 14:42:50
User entered 'Day 7'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-01T17:56:24', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '34ada585-b8f6-4a0a-b8d1-eb1adce208f8'	System	01 Oct 2020 21:56:46
User entered 'None (0)'	System	01 Oct 2020 21:56:46

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-01T17:56:26', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '34ada585-b8f6-4a0a-b8d1-eb1adce208f8'	System	01 Oct 2020 21:56:46
User entered 'None (0)'	System	01 Oct 2020 21:56:46

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-01T17:56:28', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '34ada585-b8f6-4a0a-b8d1-eb1adce208f8'	System	01 Oct 2020 21:56:46
User entered 'None (0)'	System	01 Oct 2020 21:56:46

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-01T17:56:30', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '34ada585-b8f6-4a0a-b8d1-eb1adce208f8'	System	01 Oct 2020 21:56:46
User entered 'None (0)'	System	01 Oct 2020 21:56:46

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-01T17:56:32', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '34ada585-b8f6-4a0a-b8d1-eb1adce208f8'	System	01 Oct 2020 21:56:46
User entered 'None (0)'	System	01 Oct 2020 21:56:46

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-01T17:56:33', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '34ada585-b8f6-4a0a-b8d1-eb1adce208f8'	System	01 Oct 2020 21:56:46
User entered 'None (0)'	System	01 Oct 2020 21:56:46

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-01T17:56:36', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '34ada585-b8f6-4a0a-b8d1-eb1adce208f8'	System	01 Oct 2020 21:56:46
User entered 'No (N)'	System	01 Oct 2020 21:56:46

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-01T17:56:39', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '34ada585-b8f6-4a0a-b8d1-eb1adce208f8'	System	01 Oct 2020 21:56:46
User entered '01 Oct 2020 17:56'	System	01 Oct 2020 21:56:46

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 14:42:50

US3702046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 14:42:50

US3702046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Genessi Rodriguez (b) (4)	07 Oct 2020 19:14:09

US3702046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '05 Oct 2020'	Genessi Rodriguez (b) (4)	07 Oct 2020 19:14:09

US3702046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Contact Made (CONTACT MADE)'	Genessi Rodriguez (b) (4)	07 Oct 2020 19:14:09

US3702046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Genessi Rodriguez (b) (4)	07 Oct 2020 19:14:09

US3702046

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Genessi Rodriguez (b) (4)	07 Oct 2020 19:20:10

US3702046

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User entered 'I'	System	07 Oct 2020 19:20:10

US3702046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Oct 2020 20:45:28

US3702046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '12 Oct 2020'	Jiamin Li (b) (4)	12 Oct 2020 20:45:28

US3702046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jiamin Li (b) (4)	12 Oct 2020 20:45:28

US3702046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	12 Oct 2020 20:45:34
User entered 'Participant did not pick up.' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Oct 2020 20:45:34
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	12 Oct 2020 20:45:28
User entered empty.	Jiamin Li (b) (4)	12 Oct 2020 20:45:28

US3702046

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Oct 2020 20:45:38

US3702046

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:23:38
User entered 'I'	System	12 Oct 2020 20:45:38

US3702046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Genessi Rodriguez (b) (4)	20 Oct 2020 20:09:48

US3702046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '16 Oct 2020'	Genessi Rodriguez (b) (4)	20 Oct 2020 20:09:48

US3702046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Contact Not Made (CONTACT NOT MADE)'	Genessi Rodriguez (b) (4)	20 Oct 2020 20:09:48

US3702046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Patient not able to take calls.'	Genessi Rodriguez (b) (4)	20 Oct 2020 20:09:48

US3702046

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Mia Crowley (b) (4)	23 Oct 2020 14:13:15

US3702046

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User entered 'I'	System	23 Oct 2020 14:13:15

US3702046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Yes (Y)'	Mia Crowley (b) (4)	23 Oct 2020 14:13:27

US3702046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '23 Oct 2020'	Mia Crowley (b) (4)	23 Oct 2020 14:13:27

US3702046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:45

[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 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Clinic (Clinic)'	Mia Crowley (b) (4)	23 Oct 2020 14:13:27

US3702046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User entered 'VISIT2'	System	23 Oct 2020 14:13:27

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User accepted default value 'Pre-Dose (PREDOSE)'	Jiamin Li (b) (4) (b) (4)	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Yes (Y)'	Jiamin Li (b) (4)	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '23 Oct 2020'	Jiamin Li (b) (4)	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '09:18'	Jiamin Li (b) (4)	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User entered '23 Oct 2020 09:18'	System	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '36.3' C	Jiamin Li (b) (4)	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Other (Other)'	Jiamin Li (b) (4)	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Temporal'	Jiamin Li (b) (4)	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '82'	Jiamin Li (b) (4)	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User entered 'bpm'	System	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '16'	Jiamin Li (b) (4)	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User entered 'breaths/min'	System	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '144'	Jiamin Li (b) (4)	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User entered 'mmHg'	System	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '91'	Jiamin Li (b) (4)	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User entered 'mmHg'	System	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User accepted default value 'Post-Dose (POSTDOSE)'	Jiamin Li (b) (4) (b) (4)	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Yes (Y)'	Jiamin Li (b) (4)	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '23 Oct 2020'	Jiamin Li (b) (4)	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '10:46'	Jiamin Li (b) (4)	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User entered '23 Oct 2020 10:46'	System	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '36.4' C	Jiamin Li (b) (4)	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Oral (Oral)'	Jiamin Li (b) (4)	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered empty.	Jiamin Li (b) (4)	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '76'	Jiamin Li (b) (4)	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User entered 'bpm'	System	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '16'	Jiamin Li (b) (4)	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User entered 'breaths/min'	System	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '137'	Jiamin Li (b) (4)	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User entered 'mmHg'	System	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '97'	Jiamin Li (b) (4)	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User entered 'mmHg'	System	26 Oct 2020 16:22:09

US3702046

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:19:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Yes (Y)'	Jiamin Li (b) (4)	26 Oct 2020 16:21:17

US3702046

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:19:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '23 Oct 2020'	Jiamin Li (b) (4)	26 Oct 2020 16:21:17

US3702046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Yes (Y)'	Mia Crowley (b) (4)	23 Oct 2020 14:13:57

US3702046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered empty.	Mia Crowley (b) (4)	23 Oct 2020 14:13:57

US3702046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:45

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 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered empty.	Mia Crowley (b) (4)	23 Oct 2020 14:13:57

US3702046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:45

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User entered 'MRNA-1273 OR PLACEBO'	System	23 Oct 2020 14:13:57

US3702046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:45

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '23 Oct 2020'	Mia Crowley (b) (4)	23 Oct 2020 14:13:57

US3702046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '10:08'	Mia Crowley (b) (4)	23 Oct 2020 14:13:57

US3702046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User entered '23 Oct 2020 10:08'	System	23 Oct 2020 14:13:57

US3702046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:45

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Left Arm (LEFT ARM)'	Mia Crowley (b) (4)	23 Oct 2020 14:13:57

US3702046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:45

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User entered 'ONCE'	System	23 Oct 2020 14:13:57

US3702046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:45

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User entered 'INTRAMUSCULAR'	System	23 Oct 2020 14:13:57

US3702046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Yes (Y)'	Jiamin Li (b) (4)	26 Oct 2020 16:22:50

US3702046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '23 Oct 2020'	Jiamin Li (b) (4)	26 Oct 2020 16:22:50

US3702046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '09:39'	Jiamin Li (b) (4)	26 Oct 2020 16:22:50

US3702046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User entered '23 Oct 2020 09:39'	System	26 Oct 2020 16:22:50

US3702046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:19:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '23 Oct 2020'	Jiamin Li (b) (4)	26 Oct 2020 16:22:29

US3702046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:19:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jiamin Li (b) (4) (b) (4)	26 Oct 2020 16:22:29

US3702046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:19:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Yes (Y)'	Jiamin Li (b) (4)	26 Oct 2020 16:22:29

US3702046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:19:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '10:06'	Jiamin Li (b) (4)	26 Oct 2020 16:22:29

US3702046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User entered '23 Oct 2020 10:06'	System	26 Oct 2020 16:22:29

US3702046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:19:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jiamin Li (b) (4) (b) (4)	26 Oct 2020 16:22:29

US3702046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:19:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'No (N)'	Jiamin Li (b) (4)	26 Oct 2020 16:22:29

US3702046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:19:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered empty.	Jiamin Li (b) (4)	26 Oct 2020 16:22:29

US3702046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User entered empty.	System	26 Oct 2020 16:22:29

US3702046

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Yes (Y)'	Mia Crowley (b) (4)	23 Oct 2020 14:13:33

US3702046

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User entered 'I'	System	23 Oct 2020 14:13:33

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	23 Oct 2020 14:13:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-23T10:45:08', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'bf285736-e362-4358-8d0d-69014ec49375'	System	23 Oct 2020 14:45:31
User entered 'Yes (Y)'	System	23 Oct 2020 14:45:31

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-23T10:45:16', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'bf285736-e362-4358-8d0d-69014ec49375'	System	23 Oct 2020 14:45:31
User entered '97.6'	System	23 Oct 2020 14:45:31

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-23T10:45:22', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'bf285736-e362-4358-8d0d-69014ec49375'	System	23 Oct 2020 14:45:31
User entered 'No (N)'	System	23 Oct 2020 14:45:31

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-23T10:45:25', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'bf285736-e362-4358-8d0d-69014ec49375'	System	23 Oct 2020 14:45:31
User entered '23 Oct 2020 10:45'	System	23 Oct 2020 14:45:31

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '23 Oct 2020 10:28'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '23 Oct 2020 12:58'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	23 Oct 2020 14:13:57
User entered 'Day 1, after vaccination (at home)'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '23 Oct 2020 13:53'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '24 Oct 2020 11:59'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	23 Oct 2020 14:13:57
User entered 'Day 2'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:45

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-24T12:39:23', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '9344a283-d93b-4bcc-a09e-53c92262e5c6'	System	24 Oct 2020 16:39:52
User entered 'Yes (Y)'	System	24 Oct 2020 16:39:52

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-24T12:39:30', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '9344a283-d93b-4bcc-a09e-53c92262e5c6'	System	24 Oct 2020 16:39:52
User entered '98.8'	System	24 Oct 2020 16:39:52

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-24T12:39:35', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '9344a283-d93b-4bcc-a09e-53c92262e5c6'	System	24 Oct 2020 16:39:52
User entered 'Yes (Y)'	System	24 Oct 2020 16:39:52

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Ibuprofen recorded' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 07:55:38
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Jiamin Li (b) (4)	23 Nov 2020 01:36:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-24T12:39:44', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '9344a283-d93b-4bcc-a09e-53c92262e5c6'	(b) (4)	
User entered '1'	System	24 Oct 2020 16:39:52

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-24T12:39:44', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '9344a283-d93b-4bcc-a09e-53c92262e5c6' User entered '0'	System	24 Oct 2020 16:39:52
	System	24 Oct 2020 16:39:52

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-24T12:39:48', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '9344a283-d93b-4bcc-a09e-53c92262e5c6'	System	24 Oct 2020 16:39:52
User entered '24 Oct 2020 12:39'	System	24 Oct 2020 16:39:52

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	23 Oct 2020 14:13:57
User entered 'Day 3'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-25T16:57:25', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'ad0cbeb9-19b0-486e-8dad-7080d96e188c'	System	25 Oct 2020 20:57:49
User entered 'Yes (Y)'	System	25 Oct 2020 20:57:49

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-25T16:57:33', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'ad0cbeb9-19b0-486e-8dad-7080d96e188c'	System	25 Oct 2020 20:57:49
User entered '98.4'	System	25 Oct 2020 20:57:49

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-25T16:57:36', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'ad0cbeb9-19b0-486e-8dad-7080d96e188c'	System	25 Oct 2020 20:57:49
User entered 'No (N)'	System	25 Oct 2020 20:57:49

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-25T16:57:43', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'ad0cbeb9-19b0-486e-8dad-7080d96e188c'	System	25 Oct 2020 20:57:49
User entered '25 Oct 2020 16:57'	System	25 Oct 2020 20:57:49

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	23 Oct 2020 14:13:57
User entered 'Day 4'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-26T12:56:53', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '5a487481-a290-4eaf-873c-5c4c142c6885'	System	26 Oct 2020 16:57:17
User entered 'Yes (Y)'	System	26 Oct 2020 16:57:17

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-26T12:57:00', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '5a487481-a290-4eaf-873c-5c4c142c6885'	System	26 Oct 2020 16:57:17
User entered '97.4'	System	26 Oct 2020 16:57:17

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-26T12:57:03', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '5a487481-a290-4eaf-873c-5c4c142c6885'	System	26 Oct 2020 16:57:17
User entered 'No (N)'	System	26 Oct 2020 16:57:17

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-26T12:57:10', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '5a487481-a290-4eaf-873c-5c4c142c6885'	System	26 Oct 2020 16:57:17
User entered '26 Oct 2020 12:57'	System	26 Oct 2020 16:57:17

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '26 Oct 2020 12:00'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '27 Oct 2020 11:59'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	23 Oct 2020 14:13:57
User entered 'Day 5'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:45

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-27T14:21:54', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'bd749de0-0618-4b30-9410-1d426763e2e6'	System	27 Oct 2020 18:22:13
User entered 'Yes (Y)'	System	27 Oct 2020 18:22:13

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-27T14:22:02', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'bd749de0-0618-4b30-9410-1d426763e2e6'	System	27 Oct 2020 18:22:13
User entered '98.2'	System	27 Oct 2020 18:22:13

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-27T14:22:05', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'bd749de0-0618-4b30-9410-1d426763e2e6'	System	27 Oct 2020 18:22:13
User entered 'No (N)'	System	27 Oct 2020 18:22:13

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-27T14:22:08', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'bd749de0-0618-4b30-9410-1d426763e2e6'	System	27 Oct 2020 18:22:13
User entered '27 Oct 2020 14:22'	System	27 Oct 2020 18:22:13

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '27 Oct 2020 12:00'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '28 Oct 2020 11:59'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	23 Oct 2020 14:13:57
User entered 'Day 6'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '28 Oct 2020 12:00'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '29 Oct 2020 11:59'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	23 Oct 2020 14:13:57
User entered 'Day 7'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-29T13:34:24', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '8530ecd3-d1e6-4870-9724-34e4bca11d48'	System	29 Oct 2020 17:34:45
User entered 'Yes (Y)'	System	29 Oct 2020 17:34:45

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-29T13:34:32', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '8530ecd3-d1e6-4870-9724-34e4bca11d48' User entered '97.7'	System	29 Oct 2020 17:34:45
	System	29 Oct 2020 17:34:45

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-29T13:34:35', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '8530ecd3-d1e6-4870-9724-34e4bca11d48'	System	29 Oct 2020 17:34:45
User entered 'No (N)'	System	29 Oct 2020 17:34:45

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-29T13:34:37', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '8530ecd3-d1e6-4870-9724-34e4bca11d48'	System	29 Oct 2020 17:34:45
User entered '29 Oct 2020 13:34'	System	29 Oct 2020 17:34:45

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '29 Oct 2020 12:00'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '30 Oct 2020 11:59'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	23 Oct 2020 14:13:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-23T10:44:11', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '20e74c18-8400-451b-b3df-a4900e9fc983'	System	23 Oct 2020 14:44:33
User entered 'None (1)'	System	23 Oct 2020 14:44:33

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-23T10:44:18', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '20e74c18-8400-451b-b3df-a4900e9fc983'	System	23 Oct 2020 14:44:33
User entered 'No (N)'	System	23 Oct 2020 14:44:33

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-23T10:44:21', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '20e74c18-8400-451b-b3df-a4900e9fc983'	System	23 Oct 2020 14:44:33
User entered 'No (N)'	System	23 Oct 2020 14:44:33

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-23T10:44:23', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '20e74c18-8400-451b-b3df-a4900e9fc983'	System	23 Oct 2020 14:44:33
User entered 'None (1)'	System	23 Oct 2020 14:44:33

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-23T10:44:27', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '20e74c18-8400-451b-b3df-a4900e9fc983'	System	23 Oct 2020 14:44:33
User entered '23 Oct 2020 10:44'	System	23 Oct 2020 14:44:33

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '23 Oct 2020 10:28'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '23 Oct 2020 12:58'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	23 Oct 2020 14:13:57
User entered 'Day 1, after vaccination (at home)'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '23 Oct 2020 13:53'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '24 Oct 2020 11:59'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	23 Oct 2020 14:13:57
User entered 'Day 2'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-24T12:39:57', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '19eab92b-a102-4928-baee-3347030b0d78'	System	24 Oct 2020 16:40:29
User entered 'None (1)'	System	24 Oct 2020 16:40:29

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-24T12:40:01', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '19eab92b-a102-4928-baee-3347030b0d78'	System	24 Oct 2020 16:40:29
User entered 'No (N)'	System	24 Oct 2020 16:40:29

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-24T12:40:05', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '19eab92b-a102-4928-baee-3347030b0d78'	System	24 Oct 2020 16:40:29
User entered 'Yes (Y)'	System	24 Oct 2020 16:40:29

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:45

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-24T12:40:18', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '19eab92b-a102-4928-baee-3347030b0d78'	System	24 Oct 2020 16:40:29
User entered '5'	System	24 Oct 2020 16:40:29

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-24T12:40:22', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '19eab92b-a102-4928-baee-3347030b0d78'	System	24 Oct 2020 16:40:29
User entered 'None (1)'	System	24 Oct 2020 16:40:29

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-24T12:40:25', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '19eab92b-a102-4928-baee-3347030b0d78'	System	24 Oct 2020 16:40:29
User entered '24 Oct 2020 12:40'	System	24 Oct 2020 16:40:29

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	23 Oct 2020 14:13:57
User entered 'Day 3'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-25T16:58:04', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '67ceb167-d470-4282-84ef-1a738a3bfd76'	System	25 Oct 2020 20:58:22
User entered 'Does not interfere with activity (2)'	System	25 Oct 2020 20:58:22

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-25T16:58:07', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '67ceb167-d470-4282-84ef-1a738a3bfd76'	System	25 Oct 2020 20:58:22
User entered 'No (N)'	System	25 Oct 2020 20:58:22

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-25T16:58:11', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '67ceb167-d470-4282-84ef-1a738a3bfd76'	System	25 Oct 2020 20:58:22
User entered 'No (N)'	System	25 Oct 2020 20:58:22

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-25T16:58:14', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '67ceb167-d470-4282-84ef-1a738a3bfd76'	System	25 Oct 2020 20:58:22
User entered 'None (1)'	System	25 Oct 2020 20:58:22

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-25T16:58:17', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '67ceb167-d470-4282-84ef-1a738a3bfd76'	System	25 Oct 2020 20:58:22
User entered '25 Oct 2020 16:58'	System	25 Oct 2020 20:58:22

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	23 Oct 2020 14:13:57
User entered 'Day 4'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-26T12:57:20', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'dbe69832-023b-4151-ba99-d9b80762f96b'	System	26 Oct 2020 16:58:00
User entered 'None (1)'	System	26 Oct 2020 16:58:00

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-26T12:57:22', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'dbe69832-023b-4151-ba99-d9b80762f96b'	System	26 Oct 2020 16:58:00
User entered 'No (N)'	System	26 Oct 2020 16:58:00

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-26T12:57:48', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'dbe69832-023b-4151-ba99-d9b80762f96b'	System	26 Oct 2020 16:58:00
User entered 'No (N)'	System	26 Oct 2020 16:58:00

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-26T12:57:53', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'dbe69832-023b-4151-ba99-d9b80762f96b'	System	26 Oct 2020 16:58:00
User entered 'None (1)'	System	26 Oct 2020 16:58:00

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-26T12:57:56', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'dbe69832-023b-4151-ba99-d9b80762f96b'	System	26 Oct 2020 16:58:00
User entered '26 Oct 2020 12:57'	System	26 Oct 2020 16:58:00

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '26 Oct 2020 12:00'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '27 Oct 2020 11:59'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	23 Oct 2020 14:13:57
User entered 'Day 5'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-27T14:22:16', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '229749df-bbe8-432e-a870-b5ff9f9e3b52'	System	27 Oct 2020 18:22:31
User entered 'None (1)'	System	27 Oct 2020 18:22:31

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-27T14:22:18', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '229749df-bbe8-432e-a870-b5ff9f9e3b52'	System	27 Oct 2020 18:22:31
User entered 'No (N)'	System	27 Oct 2020 18:22:31

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-27T14:22:19', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '229749df-bbe8-432e-a870-b5ff9f9e3b52'	System	27 Oct 2020 18:22:31
User entered 'No (N)'	System	27 Oct 2020 18:22:31

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-27T14:22:21', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '229749df-bbe8-432e-a870-b5ff9f9e3b52'	System	27 Oct 2020 18:22:31
User entered 'None (1)'	System	27 Oct 2020 18:22:31

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-27T14:22:24', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '229749df-bbe8-432e-a870-b5ff9f9e3b52'	System	27 Oct 2020 18:22:31
User entered '27 Oct 2020 14:22'	System	27 Oct 2020 18:22:31

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '27 Oct 2020 12:00'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '28 Oct 2020 11:59'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	23 Oct 2020 14:13:57
User entered 'Day 6'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:45

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:45

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '28 Oct 2020 12:00'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '29 Oct 2020 11:59'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	23 Oct 2020 14:13:57
User entered 'Day 7'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-29T13:34:43', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'af5acd4a-9ab0-499d-934a-fe54822d5aab'	System	29 Oct 2020 17:34:54
User entered 'None (1)'	System	29 Oct 2020 17:34:54

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-29T13:34:45', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'af5acd4a-9ab0-499d-934a-fe54822d5aab'	System	29 Oct 2020 17:34:54
User entered 'No (N)'	System	29 Oct 2020 17:34:54

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-29T13:34:47', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'af5acd4a-9ab0-499d-934a-fe54822d5aab'	System	29 Oct 2020 17:34:54
User entered 'No (N)'	System	29 Oct 2020 17:34:54

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-29T13:34:48', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'af5acd4a-9ab0-499d-934a-fe54822d5aab'	System	29 Oct 2020 17:34:54
User entered 'None (1)'	System	29 Oct 2020 17:34:54

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-29T13:34:50', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'af5acd4a-9ab0-499d-934a-fe54822d5aab'	System	29 Oct 2020 17:34:54
User entered '29 Oct 2020 13:34'	System	29 Oct 2020 17:34:54

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '29 Oct 2020 12:00'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '30 Oct 2020 11:59'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	23 Oct 2020 14:13:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-23T10:43:34', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd0d376d1-95f5-463e-8770-e1aa4212bfff'	System	23 Oct 2020 14:44:07
User entered 'None (0)'	System	23 Oct 2020 14:44:07

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-23T10:43:37', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd0d376d1-95f5-463e-8770-e1aa4212bfff'	System	23 Oct 2020 14:44:07
User entered 'None (0)'	System	23 Oct 2020 14:44:07

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-23T10:43:40', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd0d376d1-95f5-463e-8770-e1aa4212bfff'	System	23 Oct 2020 14:44:07
User entered 'None (0)'	System	23 Oct 2020 14:44:07

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-23T10:43:42', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd0d376d1-95f5-463e-8770-e1aa4212bfff'	System	23 Oct 2020 14:44:07
User entered 'None (0)'	System	23 Oct 2020 14:44:07

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-23T10:43:44', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd0d376d1-95f5-463e-8770-e1aa4212bfff'	System	23 Oct 2020 14:44:07
User entered 'None (0)'	System	23 Oct 2020 14:44:07

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-23T10:43:47', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd0d376d1-95f5-463e-8770-e1aa4212bfff'	System	23 Oct 2020 14:44:07
User entered 'None (0)'	System	23 Oct 2020 14:44:07

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-23T10:43:50', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd0d376d1-95f5-463e-8770-e1aa4212bfff'	System	23 Oct 2020 14:44:07
User entered 'No (N)'	System	23 Oct 2020 14:44:07

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-23T10:43:57', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd0d376d1-95f5-463e-8770-e1aa4212bfff'	System	23 Oct 2020 14:44:07
User entered '23 Oct 2020 10:43'	System	23 Oct 2020 14:44:07

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '23 Oct 2020 10:28'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '23 Oct 2020 12:58'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	23 Oct 2020 14:13:57
User entered 'Day 1, after vaccination (at home)'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '23 Oct 2020 13:53'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '24 Oct 2020 11:59'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	23 Oct 2020 14:13:57
User entered 'Day 2'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-24T12:38:41', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '36176159-a25f-4ebb-ad25-cbb7251dbfbf'	System	24 Oct 2020 16:39:18
User entered 'No interference with activity (1)'	System	24 Oct 2020 16:39:18

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-24T12:38:45', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '36176159-a25f-4ebb-ad25-cbb7251dbfbf'	System	24 Oct 2020 16:39:18
User entered 'No interference with activity (1)'	System	24 Oct 2020 16:39:18

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-24T12:38:48', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '36176159-a25f-4ebb-ad25-cbb7251dbfbf'	System	24 Oct 2020 16:39:18
User entered 'No interference with activity (1)'	System	24 Oct 2020 16:39:18

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-24T12:38:50', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '36176159-a25f-4ebb-ad25-cbb7251dbfbf'	System	24 Oct 2020 16:39:18
User entered 'No interference with activity (1)'	System	24 Oct 2020 16:39:18

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-24T12:38:53', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '36176159-a25f-4ebb-ad25-cbb7251dbfbf'	System	24 Oct 2020 16:39:18
User entered 'None (0)'	System	24 Oct 2020 16:39:18

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-24T12:39:00', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '36176159-a25f-4ebb-ad25-cbb7251dbfbf'	System	24 Oct 2020 16:39:18
User entered 'Some interference with activity not requiring medical attention (2)'	System	24 Oct 2020 16:39:18

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-24T12:39:06', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '36176159-a25f-4ebb-ad25-cbb7251dbfbf'	System	24 Oct 2020 16:39:18
User entered 'No (N)'	System	24 Oct 2020 16:39:18

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-24T12:39:14', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '36176159-a25f-4ebb-ad25-cbb7251dbfbf' User entered '24 Oct 2020 12:39'	System	24 Oct 2020 16:39:18
	System	24 Oct 2020 16:39:18

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	23 Oct 2020 14:13:57
User entered 'Day 3'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-25T16:58:32', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'c2708118-2429-4b7b-9331-6f3a85c4ae62'	System	25 Oct 2020 20:58:50
User entered 'None (0)'	System	25 Oct 2020 20:58:50

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-25T16:58:34', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'c2708118-2429-4b7b-9331-6f3a85c4ae62'	System	25 Oct 2020 20:58:50
User entered 'None (0)'	System	25 Oct 2020 20:58:50

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-25T16:58:36', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'c2708118-2429-4b7b-9331-6f3a85c4ae62'	System	25 Oct 2020 20:58:50
User entered 'None (0)'	System	25 Oct 2020 20:58:50

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-25T16:58:38', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'c2708118-2429-4b7b-9331-6f3a85c4ae62'	System	25 Oct 2020 20:58:50
User entered 'None (0)'	System	25 Oct 2020 20:58:50

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-25T16:58:40', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'c2708118-2429-4b7b-9331-6f3a85c4ae62'	System	25 Oct 2020 20:58:50
User entered 'None (0)'	System	25 Oct 2020 20:58:50

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-25T16:58:42', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'c2708118-2429-4b7b-9331-6f3a85c4ae62'	System	25 Oct 2020 20:58:50
User entered 'None (0)'	System	25 Oct 2020 20:58:50

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-25T16:58:45', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'c2708118-2429-4b7b-9331-6f3a85c4ae62'	System	25 Oct 2020 20:58:50
User entered 'No (N)'	System	25 Oct 2020 20:58:50

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-25T16:58:47', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'c2708118-2429-4b7b-9331-6f3a85c4ae62'	System	25 Oct 2020 20:58:50
User entered '25 Oct 2020 16:58'	System	25 Oct 2020 20:58:50

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	23 Oct 2020 14:13:57
User entered 'Day 4'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-26T12:58:01', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '2cadd13e-93cb-4fd2-84ac-d9add8eff996'	System	26 Oct 2020 17:01:01
User entered 'None (0)'	System	26 Oct 2020 17:01:01

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-26T12:58:03', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '2cadd13e-93cb-4fd2-84ac-d9add8eff996'	System	26 Oct 2020 17:01:01
User entered 'None (0)'	System	26 Oct 2020 17:01:01

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-26T13:00:14', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '2cadd13e-93cb-4fd2-84ac-d9add8eff996'	System	26 Oct 2020 17:01:01
User entered 'None (0)'	System	26 Oct 2020 17:01:01

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-26T13:00:16', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '2cadd13e-93cb-4fd2-84ac-d9add8eff996'	System	26 Oct 2020 17:01:01
User entered 'None (0)'	System	26 Oct 2020 17:01:01

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-26T13:00:18', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '2cadd13e-93cb-4fd2-84ac-d9add8eff996'	System	26 Oct 2020 17:01:01
User entered 'None (0)'	System	26 Oct 2020 17:01:01

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-26T13:00:20', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '2cadd13e-93cb-4fd2-84ac-d9add8eff996'	System	26 Oct 2020 17:01:01
User entered 'None (0)'	System	26 Oct 2020 17:01:01

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-26T13:00:23', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '2cadd13e-93cb-4fd2-84ac-d9add8eff996'	System	26 Oct 2020 17:01:01
User entered 'No (N)'	System	26 Oct 2020 17:01:01

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-26T13:00:28', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '2cadd13e-93cb-4fd2-84ac-d9add8eff996'	System	26 Oct 2020 17:01:01
User entered '26 Oct 2020 13:00'	System	26 Oct 2020 17:01:01

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '26 Oct 2020 12:00'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '27 Oct 2020 11:59'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	23 Oct 2020 14:13:57
User entered 'Day 5'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-27T14:22:28', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '3a7da944-53ea-4ffb-85b7-683881c1ce14'	System	27 Oct 2020 18:22:45
User entered 'None (0)'	System	27 Oct 2020 18:22:45

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-27T14:22:30', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '3a7da944-53ea-4ffb-85b7-683881c1ce14'	System	27 Oct 2020 18:22:45
User entered 'None (0)'	System	27 Oct 2020 18:22:45

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-27T14:22:31', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '3a7da944-53ea-4ffb-85b7-683881c1ce14'	System	27 Oct 2020 18:22:45
User entered 'None (0)'	System	27 Oct 2020 18:22:45

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-27T14:22:33', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '3a7da944-53ea-4ffb-85b7-683881c1ce14'	System	27 Oct 2020 18:22:45
User entered 'None (0)'	System	27 Oct 2020 18:22:45

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-27T14:22:36', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '3a7da944-53ea-4ffb-85b7-683881c1ce14'	System	27 Oct 2020 18:22:45
User entered 'None (0)'	System	27 Oct 2020 18:22:45

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-27T14:22:37', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '3a7da944-53ea-4ffb-85b7-683881c1ce14'	System	27 Oct 2020 18:22:45
User entered 'None (0)'	System	27 Oct 2020 18:22:45

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-27T14:22:39', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '3a7da944-53ea-4ffb-85b7-683881c1ce14'	System	27 Oct 2020 18:22:45
User entered 'No (N)'	System	27 Oct 2020 18:22:45

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-27T14:22:42', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: '3a7da944-53ea-4ffb-85b7-683881c1ce14'	System	27 Oct 2020 18:22:45
User entered '27 Oct 2020 14:22'	System	27 Oct 2020 18:22:45

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '27 Oct 2020 12:00'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '28 Oct 2020 11:59'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	23 Oct 2020 14:13:57
User entered 'Day 6'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '28 Oct 2020 12:00'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '29 Oct 2020 11:59'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
Data entry locked.	System	23 Oct 2020 14:13:57
User entered 'Day 7'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-29T13:34:56', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd020fddb-0ea4-44ac-aa8a-c6b9396e5a3b'	System	29 Oct 2020 17:35:11
User entered 'None (0)'	System	29 Oct 2020 17:35:11

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-29T13:34:57', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd020fddb-0ea4-44ac-aa8a-c6b9396e5a3b'	System	29 Oct 2020 17:35:11
User entered 'None (0)'	System	29 Oct 2020 17:35:11

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-29T13:34:58', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd020fddb-0ea4-44ac-aa8a-c6b9396e5a3b'	System	29 Oct 2020 17:35:11
User entered 'None (0)'	System	29 Oct 2020 17:35:11

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-29T13:35:00', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd020fddb-0ea4-44ac-aa8a-c6b9396e5a3b'	System	29 Oct 2020 17:35:11
User entered 'None (0)'	System	29 Oct 2020 17:35:11

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-29T13:35:01', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd020fddb-0ea4-44ac-aa8a-c6b9396e5a3b'	System	29 Oct 2020 17:35:11
User entered 'None (0)'	System	29 Oct 2020 17:35:11

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-29T13:35:03', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd020fddb-0ea4-44ac-aa8a-c6b9396e5a3b'	System	29 Oct 2020 17:35:11
User entered 'None (0)'	System	29 Oct 2020 17:35:11

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:45

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 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-29T13:35:05', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd020fdbb-0ea4-44ac-aa8a-c6b9396e5a3b'	System	29 Oct 2020 17:35:11
User entered 'No (N)'	System	29 Oct 2020 17:35:11

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77be809ebf88f9c3)', Time: '2020-10-29T13:35:07', User OID: 'PatientReportedOutcome (US3702046)', ODM File OID: 'd020fddb-0ea4-44ac-aa8a-c6b9396e5a3b'	System	29 Oct 2020 17:35:11
User entered '29 Oct 2020 13:35'	System	29 Oct 2020 17:35:11

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '29 Oct 2020 12:00'	System	23 Oct 2020 14:13:57

US3702046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:53:21
User entered '30 Oct 2020 11:59'	System	23 Oct 2020 14:13:57

US3702046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	09 Nov 2020 22:01:39

US3702046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '30 Oct 2020'	Jiamin Li (b) (4)	09 Nov 2020 22:01:39

US3702046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
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 22:01:39

US3702046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered empty.	Jiamin Li (b) (4)	09 Nov 2020 22:01:39

US3702046

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	09 Nov 2020 22:01:43

US3702046

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User entered 'I'	System	09 Nov 2020 22:01:43

US3702046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	09 Nov 2020 22:04:08

US3702046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered '09 Nov 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	19 Jan 2021 13:15:47
User entered '06 Nov 2020'	Jiamin Li (b) (4)	09 Nov 2020 22:04:08

US3702046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Jiamin Li (b) (4)	09 Nov 2020 22:04:34
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	09 Nov 2020 22:04:08

US3702046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	09 Nov 2020 22:04:40
User entered 'Participant did not pick up' reason for change: Data Entry Error	Jiamin Li (b) (4)	09 Nov 2020 22:04:40
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	09 Nov 2020 22:04:34
User entered empty.	Jiamin Li (b) (4)	09 Nov 2020 22:04:08

US3702046

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	09 Nov 2020 22:05:02

US3702046

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User entered 'I'	System	09 Nov 2020 22:05:02

US3702046

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	09 Nov 2020 22:05:21

US3702046

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	29 Nov 2020 16:51:50
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Contact attempt first made starting on 11/6/2020, but participant never picked up.' (Site from System).	Jiamin Li (b) (4)	09 Nov 2020 22:05:54
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Nov 2020 22:05:21
User entered '09 Nov 2020'	Jiamin Li (b) (4)	09 Nov 2020 22:05:21

US3702046

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jiamin Li (b) (4)	09 Nov 2020 22:05:21

US3702046

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Participant did not pick up'	Jiamin Li (b) (4)	09 Nov 2020 22:05:21

US3702046

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:35
User entered 'Yes (Y)'	Jiamin Li (b) (4)	09 Nov 2020 22:05:25

US3702046

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User entered 'I'	System	09 Nov 2020 22:05:25

US3702046

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Yes (Y)'	Mia Crowley (b) (4)	19 Nov 2020 15:45:12

US3702046

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '19 Nov 2020'	Mia Crowley (b) (4)	19 Nov 2020 15:45:12

US3702046

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:45

[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 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Clinic (Clinic)'	Mia Crowley (b) (4)	19 Nov 2020 15:45:12

US3702046

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User entered 'VISIT3'	System	19 Nov 2020 15:45:12

US3702046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Yes (Y)'	Jiamin Li (b) (4)	23 Nov 2020 01:40:08

US3702046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '19 Nov 2020'	Jiamin Li (b) (4)	23 Nov 2020 01:40:08

US3702046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '10:00'	Jiamin Li (b) (4)	23 Nov 2020 01:40:08

US3702046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User entered '19 Nov 2020 10:00'	System	23 Nov 2020 01:40:08

US3702046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
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)	29 Nov 2020 16:51:40
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)	23 Nov 2020 01:40:26
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	23 Nov 2020 01:40:08
User entered '35.8' C	Jiamin Li (b) (4)	23 Nov 2020 01:40:08

US3702046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Other (Other)'	Jiamin Li (b) (4)	23 Nov 2020 01:40:08

US3702046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Information not known'	Jiamin Li (b) (4)	23 Nov 2020 01:40:08

US3702046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '100'	Jiamin Li (b) (4)	23 Nov 2020 01:40:08

US3702046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User entered 'bpm'	System	23 Nov 2020 01:40:08

US3702046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '14'	Jiamin Li (b) (4)	23 Nov 2020 01:40:08

US3702046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User entered 'breaths/min'	System	23 Nov 2020 01:40:08

US3702046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '129'	Jiamin Li (b) (4)	23 Nov 2020 01:40:08

US3702046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User entered 'mmHg'	System	23 Nov 2020 01:40:08

US3702046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '91'	Jiamin Li (b) (4)	23 Nov 2020 01:40:08

US3702046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User entered 'mmHg'	System	23 Nov 2020 01:40:08

US3702046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07

US3702046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:45

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07

US3702046

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:19:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Yes (Y)'	Jiamin Li (b) (4)	23 Nov 2020 01:39:23

US3702046

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:19:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '19 Nov 2020'	Jiamin Li (b) (4)	23 Nov 2020 01:39:23

US3702046

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Yes (Y)'	Jiamin Li (b) (4)	23 Nov 2020 01:40:38

US3702046

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '19 Nov 2020'	Jiamin Li (b) (4)	23 Nov 2020 01:40:38

US3702046

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:45

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered '09:46'	Jiamin Li (b) (4)	23 Nov 2020 01:40:38

US3702046

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User entered '19 Nov 2020 09:46'	System	23 Nov 2020 01:40:38

US3702046

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User signature succeeded.	Kristen Marks (b) (4)	23 Feb 2021 19:21:45
User entered 'Yes (Y)'	Mia Crowley (b) (4)	19 Nov 2020 15:45:19

US3702046

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:23:07
User entered 'I'	System	19 Nov 2020 15:45:19

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '20 Nov 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '24 Nov 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '27 Nov 2022 00:01'	System	20 Nov 2020 10:46:14

US3702046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:46:14
Amendment Manager: User entered '01 Dec 2022 23:59'	System	20 Nov 2020 10:46:14

US3702046

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:56:59
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Dec 2020 18:36:18

US3702046

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:56:59
User entered '18 Dec 2020'	Jiamin Li (b) (4)	22 Dec 2020 18:36:18

US3702046

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:56:59
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	22 Dec 2020 18:36:18

US3702046

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:56:59
User entered empty.	Jiamin Li (b) (4)	22 Dec 2020 18:36:18

US3702046

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:56:59
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Dec 2020 18:36:25

US3702046

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:22:46
User entered 'I'	System	22 Dec 2020 18:36:25

US3702046

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered 'Yes (Y)'	Jiamin Li (b) (4)	09 Mar 2021 02:27:34

US3702046

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered '21 Jan 2021'	Jiamin Li (b) (4)	09 Mar 2021 02:27:34

US3702046

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	09 Mar 2021 02:27:34

US3702046

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered empty.	Jiamin Li (b) (4)	09 Mar 2021 02:27:34

US3702046

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered 'Yes (Y)'	Jiamin Li (b) (4)	09 Mar 2021 02:26:56

US3702046

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:28
User entered 'I'	System	09 Mar 2021 02:26:56

US3702046

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered 'Yes (Y)'	Jiamin Li (b) (4)	09 Mar 2021 02:27:05

US3702046

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered '18 Feb 2021'	Jiamin Li (b) (4)	09 Mar 2021 02:27:05

US3702046

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	09 Mar 2021 02:27:05

US3702046

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered empty.	Jiamin Li (b) (4)	09 Mar 2021 02:27:05

US3702046

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered 'Yes (Y)'	Jiamin Li (b) (4)	09 Mar 2021 02:27:09

US3702046

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:28
User entered 'I'	System	09 Mar 2021 02:27:09

US3702046

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered 'Yes (Y)'	Jiamin Li (b) (4)	31 Mar 2021 00:49:19

US3702046

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered '23 Mar 2021'	Jiamin Li (b) (4)	31 Mar 2021 00:49:19

US3702046

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jiamin Li (b) (4)	31 Mar 2021 00:49:19

US3702046

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered 'Participant did not pick up after multiple attempts.'	Jiamin Li (b) (4)	31 Mar 2021 00:49:19

US3702046

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered 'Yes (Y)'	Jiamin Li (b) (4)	31 Mar 2021 00:48:38

US3702046

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:29:28
User entered 'I'	System	31 Mar 2021 00:48:38

US3702046

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

Form: Visit Date

Generated On: 10 Jun 2021 09:19:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered 'Yes (Y)'	Mia Crowley (b) (4)	22 Jan 2021 20:04:49

US3702046

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

Form: Visit Date

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered '22 Jan 2021'	Mia Crowley (b) (4)	22 Jan 2021 20:04:49

US3702046

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

Form: Visit Date

Generated On: 10 Jun 2021 09:19:45

[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 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered 'Clinic (Clinic)'	Mia Crowley (b) (4)	22 Jan 2021 20:04:49

US3702046

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

Form: Visit Date

Generated On: 10 Jun 2021 09:19:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered 'UNBLND_DECIDE'	System	22 Jan 2021 20:04:49

US3702046

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

Form: Unblinding

Generated On: 10 Jun 2021 09:19:45

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered '22 Jan 2021'	Mia Crowley (b) (4)	22 Jan 2021 20:05:10

US3702046

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

Form: Unblinding

Generated On: 10 Jun 2021 09:19:45

[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 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered '0'	Jiamin Li (b) (4)	09 Mar 2021 02:26:06
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:59:00

US3702046

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

Form: Unblinding

Generated On: 10 Jun 2021 09:19:45

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered 'Yes (Y)'	Mia Crowley (b) (4)	22 Jan 2021 20:05:10

US3702046

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

Form: Unblinding

Generated On: 10 Jun 2021 09:19:45

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered 'Amendment 6 or later (Amendment 6 or later)'	Jiamin Li (b) (4)	09 Mar 2021 02:26:06
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:59:00

US3702046

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

Form: Unblinding

Generated On: 10 Jun 2021 09:19:45

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered '22 Jan 2021'	Mia Crowley (b) (4)	22 Jan 2021 20:05:10

US3702046

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

Form: Unblinding

Generated On: 10 Jun 2021 09:19:45

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered 'mRNA-1273 (mRNA-1273)'	Mia Crowley (b) (4)	22 Jan 2021 20:05:10

US3702046

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

Form: Unblinding

Generated On: 10 Jun 2021 09:19:45

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered 'mRNA-1273 (mRNA-1273)'	Mia Crowley (b) (4)	22 Jan 2021 20:05:10

US3702046

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

Form: Unblinding

Generated On: 10 Jun 2021 09:19:45

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered 'mRNA-1273 (mRNA-1273)'	Mia Crowley (b) (4)	22 Jan 2021 20:05:10

US3702046

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

Form: Unblinding

Generated On: 10 Jun 2021 09:19:45

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered 'No (N)'	Mia Crowley (b) (4)	22 Jan 2021 20:05:10

US3702046

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

Form: Unblinding

Generated On: 10 Jun 2021 09:19:45

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered empty.	System	22 Jan 2021 20:05:10

US3702046

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

Form: Unblinding

Generated On: 10 Jun 2021 09:19:45

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered empty.	System	22 Jan 2021 20:05:10

US3702046

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered 'Yes (Y)'	Mia Crowley (b) (4)	22 Jan 2021 20:05:22

US3702046

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered '22 Jan 2021'	Mia Crowley (b) (4)	22 Jan 2021 20:05:22

US3702046

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:45

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered '12:35'	Mia Crowley (b) (4)	22 Jan 2021 20:05:22

US3702046

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered '22 Jan 2021 12:35'	System	22 Jan 2021 20:05:22

US3702046

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:19:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered 'Yes (Y)'	Mia Crowley (b) (4)	22 Jan 2021 20:05:33

US3702046

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered '22 Jan 2021'	Mia Crowley (b) (4)	22 Jan 2021 20:05:33

US3702046

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:19:45

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered '12:31'	Mia Crowley (b) (4)	22 Jan 2021 20:05:33

US3702046

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:42
User entered '22 Jan 2021 12:31'	System	22 Jan 2021 20:05:33

US3702046

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:19:45

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:55
User signature succeeded.	Kristen Marks (b) (4)	03 May 2021 19:29:34
Signature has been broken.	Jiamin Li (b) (4)	30 Apr 2021 02:46:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	30 Apr 2021 02:46:13
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:44:12
User entered 'No (N)'	Genessi Rodriguez (b) (4)	07 Oct 2020 20:10:37

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:30:38
User entered 'USA-US133-2021-mRNA-1273-P301000005'	(b) (4), (b) (6)	03 May 2021 14:30:32

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as SOC: Psychiatric disorders, HLT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar I disorder, LLT: Manic depressive psychosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 18:10:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 18:10:11
Data point term sent to Coder	System	30 Apr 2021 17:01:22
User entered 'Bipolar disorder with psychosis'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '26 Feb 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '09 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:55:16
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	01 May 2021 11:08:11
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Participant passed away, never discharged.' (Site from System).	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:55:24
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	30 Apr 2021 18:55:16
User entered '1' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:55:16
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '26 Feb 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	30 Apr 2021 18:55:16
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '09 Mar 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	30 Apr 2021 18:57:47
User entered empty.	Jiamin Li (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	30 Apr 2021 18:55:16
User entered empty.	Jiamin Li (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '1' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:55:16
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Not Applicable (NOT APPLICABLE)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '1'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 18:55:16
User entered '0'	System	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 17:00:33

US3702046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:45

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 18:55:16

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Lumbar pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 18:44:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 18:44:02
Data point term sent to Coder	System	30 Apr 2021 18:43:52
Coding entries removed.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:43:44
User entered 'Lumbar BACK PAIN' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:43:44
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 17:03:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 17:03:55
Data point term sent to Coder	System	30 Apr 2021 17:03:23
User entered 'Back pain'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '27 Feb 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '09 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Not Applicable (NOT APPLICABLE)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '1'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 17:02:41

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:13:51
User entered 'USA-US133-2021-mRNA-1273-P301000005'	System	30 Apr 2021 18:13:36
User entered 'New'	(b) (4), (b) (6)	30 Apr 2021 18:13:36

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 17:10:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 17:10:58
Data point term sent to Coder	System	30 Apr 2021 17:10:29
User entered 'Pulmonary Embolism'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '01 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '09 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Grade 4 (Grade 4)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '1'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '1' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:54:20
User entered '0' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:49:09
User entered '1'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	01 May 2021 11:08:43
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		30 Apr 2021 18:50:20
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		30 Apr 2021 18:50:20
User entered '1' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:50:20
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	30 Apr 2021 18:49:09
User entered '0' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:49:09
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Patient was not discharged. Patient passed away.' (Site from System).	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:34
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	30 Apr 2021 17:10:10
User entered '1'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '26 Feb 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '09 Mar 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	30 Apr 2021 18:58:08
User entered empty.	Jiamin Li (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	03 May 2021 19:29:34
	(b) (4)	
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	30 Apr 2021 18:50:20
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	30 Apr 2021 18:50:20
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	30 Apr 2021 18:49:09
User entered 'I'	Jiamin Li (b) (4)	30 Apr 2021 17:10:10
	(b) (4)	

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Not Applicable (NOT APPLICABLE)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '1'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Fatal (FATAL)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Pt is a 50 year old male(IP arm, last visit OL3 visit 22JAN2021). On 26FEB21 pt presented to the Psychiatric Evaluation Program-Jacobi Hospital with the following: bizarre behavior, selective mutism, agitation, stripping of clothing. PMH: bipolar disorder, hypertension, diabetes mellitus, sleep apnea. Pt ran headfirst into a wall; requiring restraint. Head CTS and CXR neg. Transferred to Psychiatry. Started on lithium, haloperidol, Ativan. Denied ETOH/illicit substance use. Afebrile. Neg COVID swab. WBC elevated. Day 4, the pt c/o new onset SOB. Tachycardia and LE edema noted. CT-Angiogram showed multiple segmental/subsegmental pulmonary emboli, left worse than right. Anticoagulation with Lovenox 120mg q12h started. Day 5 MS altered. ABG done--PaO2 = 77. Ativan and Lithium were d/c'd. Mental status improved. Urinary retention req. foley cath. TEE revealed normal LVEF and no RV strain. Duplex study was also negative for DVT. Hypercoagulability workup neg. Levenox changed to abixaban 5mg bid Day 8. Pt found unresponsive on morning of day 9. Noted to be confused, diaphoretic, tremulous. Left conjunctivitis, purulent discharge, lesions noted. CXR nL, UrCx neg. Abixaban changed to Lovenox. On Day 11 COVID swab neg Day 12 Episode of rectal bleeding with clots. Febrile to 102.6F. Tachycardic. BP nL, Os sat 95%. Found shortly thereafter to be unresponsive. Resuscitation unsuccessful. Time of death 1:59 PM.' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:30:21
User entered empty; reason for change Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:47

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[Narrative](#)

Audit	User	Time (GMT)
User entered (b) (6) was a 50 year old male COVE participant (IP arm, last seen at OL3 visit on 2/18/21) that initially presented via EMS to the Comprehensive Psychiatric Evaluation Program (CPEP) at Jacobi Hospital with bizarre behavior witnessed at home and was admitted to the psychiatry unit on 2/26/2021. His behavior in CPEP was consistent with historically documented behaviors: selective mutism, agitation, and stripping of clothing. His PHM at this facility included bipolar disorder, hypertension, and diabetes mellitus. His initial agitation at admission included an event where he ran head first into a wall/door, which necessitated physical and chemical restraints and a transfer to the medical ER for workup. A negative head CT and negative CXR were noted at this time. After medical clearance, he was returned to CPEP where his home meds were also restarted and he eventually became cooperative, agreed to be admitted to psychiatric hold, and to restart Lithium therapy that he admitted to stopping 4-5 years before. He denied any recent alcohol or recreational drug use. His initial labs showed leukocytosis, patient was afebrile, and a negative COVID PCR test was obtained. When seen on the medical floor on 3/2 the patient was acutely altered and not answering questions, barely speaking, and following commands but with a delay. The sitter at the bedside stated that he had been like this for about an hour. An ABG was performed and he was placed on CPAP.'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:19:45

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 17:10:10

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Eye and eyelid infections, PT: Conjunctivitis, LLT: Conjunctivitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 18:48:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 18:48:19
Data point term sent to Coder	System	30 Apr 2021 18:47:54
User entered 'Conjunctivitis'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '06 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '09 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Not Applicable (NOT APPLICABLE)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'I'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:19:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 18:47:16

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Tremor (excl congenital), PT: Tremor, LLT: Tremor limb - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 May 2021 17:03:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 May 2021 17:03:10
Data point term sent to Coder	System	30 Apr 2021 18:54:00
User entered 'Upper Extremity Tremor'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '06 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '09 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Not Applicable (NOT APPLICABLE)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '1'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 18:53:40

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:32:50
User entered 'USA-US133-2021-mRNA-1273-P301000005'	(b) (4), (b) (6)	03 May 2021 14:32:44

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal haemorrhages NEC, HLT: Non-site specific gastrointestinal haemorrhages, PT: Gastrointestinal haemorrhage, LLT: Gastrointestinal bleed - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 18:58:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 18:58:05
Data point term sent to Coder	System	30 Apr 2021 18:57:03
User entered 'Gastrointestinal bleed'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '09 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '09 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User closed query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	30 Apr 2021 18:57:28
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:57:28
User opened query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	30 Apr 2021 18:56:36
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '1'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '1'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '1'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '26 Feb 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '09 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '1'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Not Applicable (NOT APPLICABLE)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '1'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Fatal (FATAL)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:45

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 18:56:36

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	03 May 2021 19:29:34
	(b) (4)	
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)	30 Apr 2021 19:00:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Apr 2021 19:00:05
Data point term sent to Coder	System	30 Apr 2021 18:59:07
User entered 'Fever'	Jiamin Li (b) (4)	30 Apr 2021 18:58:59
	(b) (4)	

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '09 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '09 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Not Applicable (NOT APPLICABLE)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '1'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 18:58:59

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:38:14
User entered 'USA-US133-2021-mRNA-1273-P301000005'	(b) (4), (b) (6)	03 May 2021 14:37:52

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Pulseless electrical activity, LLT: Pulseless electrical activity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 19:01:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 19:01:06
Data point term sent to Coder	System	30 Apr 2021 19:00:26
User entered 'Pulseless electrical activity'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '09 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '09 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Grade 4 (Grade 4)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	03 May 2021 19:29:34
	(b) (4)	
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	30 Apr 2021 19:36:21
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	30 Apr 2021 19:36:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	30 Apr 2021 19:36:21
	(b) (4)	
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	30 Apr 2021 18:59:28
User entered 'No (N)'	Jiamin Li (b) (4)	30 Apr 2021 18:59:28
	(b) (4)	

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '1' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:36:21
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '1' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:36:21
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Not Applicable (NOT APPLICABLE)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '1'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Fatal (FATAL)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Pt is a 50 year old male(IP arm, last visit OL3 visit 22JAN2021). On 26FEB21 pt presented to the Psychiatric Evaluation Program-Jacobi Hospital with the following: bizarre behavior, selective mutism, agitation, stripping of clothing. PMH: bipolar disorder, hypertension, diabetes mellitus, sleep apnea. Pt ran headfirst into a wall; requiring restraint. Head CTS and CXR neg. Transferred to Psychiatry. Started on lithium, haloperidol, Ativan. Denied ETOH/illicit substance use. Afebrile. Neg COVID swab. WBC elevated. Day 4, the pt c/o new onset SOB. Tachycardia and LE edema noted. CT-Angiogram showed multiple segmental/subsegmental pulmonary emboli, left worse than right. Anticoagulation with Lovenox 120mg q12h started. Day 5 MS altered. ABG done--PaO2 = 77. Ativan and Lithium were d/c'd. Mental status improved. Urinary retention req. foley cath. TEE revealed normal LVEF and no RV strain. Duplex study was also negative for DVT. Hypercoagulability workup neg. Levenox changed to abixaban 5mg bid Day 8. Pt found unresponsive on morning of day 9. Noted to be confused, diaphoretic, tremulous. Left conjunctivitis, purulent discharge, lesions noted. CXR nL, UrCx neg. Abixaban changed to Lovenox. On Day 11 COVID swab neg Day 12 Episode of rectal bleeding with clots. Febrile to 102.6F. Tachycardic. BP nL, Os sat 95%. Found shortly thereafter to be unresponsive. Resuscitation unsuccessful. Time of death 1:59 PM.' reason for change: Data Entry Error User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:36:21
	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 19:36:21
User entered '0'	System	30 Apr 2021 18:59:28

US3702046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:19:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 18:59:28

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:19:45

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:38
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered 'Yes (Y)'	Genessi Rodriguez (b) (4)	07 Oct 2020 19:56:24

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 20:17:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 20:17:26
Data point term sent to Coder	System	07 Oct 2020 19:59:00
User entered 'Ibuprofen'	Genessi Rodriguez (b) (4) (b) (4)	07 Oct 2020 19:58:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'No (N)'	Genessi Rodriguez (b) (4) (b) (4)	07 Oct 2020 19:58:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User closed query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 20:27:00
Query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' answered with 'Ediary sx not reportable per ae reporting criteria.' (Site from DM).	Jiamin Li (b) (4) (b) (4)	22 Dec 2020 18:37:01
User opened query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 01:53:07
User entered 'Headache'	Genessi Rodriguez (b) (4) (b) (4)	07 Oct 2020 19:58:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Signature has been broken.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:27:44
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered '200'	Genessi Rodriguez (b) (4) (b) (4)	07 Oct 2020 19:58:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'mg (mg)'	Genessi Rodriguez (b) (4) (b) (4)	07 Oct 2020 19:58:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered empty.	Genessi Rodriguez (b) (4) (b) (4)	07 Oct 2020 19:58:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'once (ONCE)'	Genessi Rodriguez (b) (4) (b) (4)	07 Oct 2020 19:58:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered empty.	Genessi Rodriguez (b) (4) (b) (4)	07 Oct 2020 19:58:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'Oral (ORAL)'	Genessi Rodriguez (b) (4) (b) (4)	07 Oct 2020 19:58:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered empty.	Genessi Rodriguez (b) (4) (b) (4)	07 Oct 2020 19:58:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered '28 Sep 2020'	Genessi Rodriguez (b) (4) (b) (4)	07 Oct 2020 19:58:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered '0'	Genessi Rodriguez (b) (4) (b) (4)	07 Oct 2020 19:58:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'No (N)'	Genessi Rodriguez (b) (4) (b) (4)	07 Oct 2020 19:58:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered '28 Sep 2020'	Genessi Rodriguez (b) (4) (b) (4)	07 Oct 2020 19:58:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'No (N)'	Genessi Rodriguez (b) (4) (b) (4)	07 Oct 2020 19:58:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:58:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:58:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:58:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 23:43:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 23:43:23
Data point term sent to Coder	System	12 Oct 2020 20:38:14
User entered 'Lisinopril'	Jiamin Li (b) (4) (b) (4)	12 Oct 2020 20:37:24

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	12 Oct 2020 20:37:24

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'High blood pressure disorder'	Jiamin Li (b) (4) (b) (4)	12 Oct 2020 20:37:24

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered '10'	Jiamin Li (b) (4) (b) (4)	12 Oct 2020 20:37:24

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	12 Oct 2020 20:37:24

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered empty.	Jiamin Li (b) (4) (b) (4)	12 Oct 2020 20:37:24

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'once daily (QD)'	Jiamin Li (b) (4) (b) (4)	12 Oct 2020 20:37:24

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered empty.	Jiamin Li (b) (4) (b) (4)	12 Oct 2020 20:37:24

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'Oral (ORAL)'	Jiamin Li (b) (4) (b) (4)	12 Oct 2020 20:37:24

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered empty.	Jiamin Li (b) (4) (b) (4)	12 Oct 2020 20:37:24

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered empty.	Jiamin Li (b) (4) (b) (4)	12 Oct 2020 20:37:24

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'I'	Jiamin Li (b) (4) (b) (4)	12 Oct 2020 20:37:24

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	12 Oct 2020 20:37:24

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered empty.	Jiamin Li (b) (4) (b) (4)	12 Oct 2020 20:37:24

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	12 Oct 2020 20:37:24

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 20:37:24

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 20:37:24

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Oct 2020 20:37:24

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 20:58:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 20:58:35
Data point term sent to Coder	System	09 Nov 2020 22:03:58
User entered 'Ibuprofen'	Jiamin Li (b) (4) (b) (4)	09 Nov 2020 22:03:25

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	09 Nov 2020 22:03:25

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'Headache prevention'	Jiamin Li (b) (4) (b) (4)	09 Nov 2020 22:03:25

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 20:27:13
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'Patient reported dose. We have no other information.' (Site from DM).	Jiamin Li (b) (4) (b) (4)	22 Dec 2020 18:37:18
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 00:11:38
User entered '250'	Jiamin Li (b) (4) (b) (4)	09 Nov 2020 22:03:25

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	09 Nov 2020 22:03:25

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered empty.	Jiamin Li (b) (4) (b) (4)	09 Nov 2020 22:03:25

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'once (ONCE)'	Jiamin Li (b) (4) (b) (4)	09 Nov 2020 22:03:25

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered empty.	Jiamin Li (b) (4) (b) (4)	09 Nov 2020 22:03:25

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'Oral (ORAL)'	Jiamin Li (b) (4) (b) (4)	09 Nov 2020 22:03:25

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered empty.	Jiamin Li (b) (4) (b) (4)	09 Nov 2020 22:03:25

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered '24 Oct 2020'	Jiamin Li (b) (4) (b) (4)	09 Nov 2020 22:03:25

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered '0'	Jiamin Li (b) (4) (b) (4)	09 Nov 2020 22:03:25

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	09 Nov 2020 22:03:25

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered '24 Oct 2020'	Jiamin Li (b) (4) (b) (4)	09 Nov 2020 22:03:25

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	09 Nov 2020 22:03:25

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 22:03:25

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 22:03:25

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 22:03:25

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 07:46:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 07:46:32
Data point term sent to Coder	System	23 Nov 2020 01:39:58
User entered 'Multivitamin (brand unknown)'	Jiamin Li (b) (4) (b) (4)	23 Nov 2020 01:39:13

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	23 Nov 2020 01:39:13

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'General health supplement'	Jiamin Li (b) (4) (b) (4)	23 Nov 2020 01:39:13

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'Unknown'	Jiamin Li (b) (4) (b) (4)	23 Nov 2020 01:39:13

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'Other (OTHER)'	Jiamin Li (b) (4) (b) (4)	23 Nov 2020 01:39:13

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'Unknown'	Jiamin Li (b) (4) (b) (4)	23 Nov 2020 01:39:13

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'unknown (UNKNOWN)'	Jiamin Li (b) (4) (b) (4)	23 Nov 2020 01:39:13

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered empty.	Jiamin Li (b) (4) (b) (4)	23 Nov 2020 01:39:13

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'Oral (ORAL)'	Jiamin Li (b) (4) (b) (4)	23 Nov 2020 01:39:13

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered empty.	Jiamin Li (b) (4) (b) (4)	23 Nov 2020 01:39:13

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered '12 Nov 2020'	Jiamin Li (b) (4) (b) (4)	23 Nov 2020 01:39:13

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered '0'	Jiamin Li (b) (4) (b) (4)	23 Nov 2020 01:39:13

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	23 Nov 2020 01:39:13

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered empty.	Jiamin Li (b) (4) (b) (4)	23 Nov 2020 01:39:13

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	23 Nov 2020 01:39:13

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 01:39:13

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 01:39:13

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 01:39:13

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User closed query 'Per MM, please confirm if this vaccination meets the EC #9 'Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).' and please raise a PD accordingly. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 19:25:09
Query 'Per MM, please confirm if this vaccination meets the EC #9 'Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).' and please raise a PD accordingly. ' answered with 'Confirmed this occurred prior to study entry' (Site from DM).	Jiamin Li (b) (4) (b) (4)	12 Apr 2021 18:10:32
User opened query 'Per MM, please confirm if this vaccination meets the EC #9 'Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).' and please raise a PD accordingly. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 19:23:38
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 18:38:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 18:38:47
Data point term sent to Coder	System	22 Dec 2020 18:38:34
User entered 'Influenza Vaccination'	Jiamin Li (b) (4) (b) (4)	22 Dec 2020 18:37:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	22 Dec 2020 18:37:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'Influenza Prophylaxis'	Jiamin Li (b) (4) (b) (4)	22 Dec 2020 18:37:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'unknown'	Jiamin Li (b) (4) (b) (4)	22 Dec 2020 18:37:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'Other (OTHER)'	Jiamin Li (b) (4) (b) (4)	22 Dec 2020 18:37:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'unknown'	Jiamin Li (b) (4) (b) (4)	22 Dec 2020 18:37:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'once (ONCE)'	Jiamin Li (b) (4) (b) (4)	22 Dec 2020 18:37:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered empty.	Jiamin Li (b) (4) (b) (4)	22 Dec 2020 18:37:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'Intramuscular (INTRAMUSCULAR)'	Jiamin Li (b) (4) (b) (4)	22 Dec 2020 18:37:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered empty.	Jiamin Li (b) (4) (b) (4)	22 Dec 2020 18:37:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'un Sep 2020'	Jiamin Li (b) (4) (b) (4)	22 Dec 2020 18:37:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered '0'	Jiamin Li (b) (4) (b) (4)	22 Dec 2020 18:37:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	22 Dec 2020 18:37:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'un Sep 2020'	Jiamin Li (b) (4) (b) (4)	22 Dec 2020 18:37:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:35:13
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	22 Dec 2020 18:37:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Dec 2020 18:37:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Dec 2020 18:37:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Dec 2020 18:37:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 15:48:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 15:48:07
Data point term sent to Coder	System	30 Apr 2021 19:04:28
User entered 'Lorazepam'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:03:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:03:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Agitation (related to Bipolar Disorder with Psychosis)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:03:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '2'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:03:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:03:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:03:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 20:25:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Apr 2021 20:25:27
User entered 'other (OTHER)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:25:27
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 19:03:59
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:03:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Twice' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:25:27
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:03:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Intramuscular (INTRAMUSCULAR)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:03:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:03:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '26 Feb 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:03:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:03:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:03:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '28 Feb 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:03:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:03:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 19:03:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 19:03:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 19:03:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: BUTYROPHENONE DERIVATIVES, PRODUCT: HALOPERIDOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 13:52:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 13:52:36
Data point term sent to Coder	System	30 Apr 2021 19:05:29
User entered 'Haloperidol'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:04:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:04:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Psychosis (related to Bipolar Disorder)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:04:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '5'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:04:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:04:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:04:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	03 May 2021 19:29:34
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 20:25:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Apr 2021 20:25:39
User entered 'once daily (QD)' reason for change: Data Entry Error	Jiamin Li (b) (4)	30 Apr 2021 20:25:39
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 19:04:34
User entered empty.	Jiamin Li (b) (4)	30 Apr 2021 19:04:34
	(b) (4)	

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:04:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Intramuscular (INTRAMUSCULAR)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:04:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:04:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '26 Feb 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:04:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:04:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:04:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '26 Feb 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:04:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:04:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 20:25:39
User entered empty.	System	30 Apr 2021 19:04:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 20:25:39
User entered empty.	System	30 Apr 2021 19:04:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 20:25:39
User entered empty.	System	30 Apr 2021 19:04:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 19:12:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 19:12:08
Data point term sent to Coder	System	30 Apr 2021 19:11:34
Data point term sent to Coder	System	30 Apr 2021 19:06:30
User entered 'Humalog'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:05:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:05:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Diabetes Mellitus' reason for change:	Jiamin Li (b) (4)	30 Apr 2021 19:10:38
Data Entry Error	(b) (4)	
User entered 'DM'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:05:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0-6'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:05:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'IU (IU)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:05:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:05:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 20:25:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Apr 2021 20:25:49
User entered 'three times daily (TID)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:25:49
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 19:05:40
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:05:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:05:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:05:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:05:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '27 Feb 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:05:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:05:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:05:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '08 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:05:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:05:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	30 Apr 2021 20:25:49
User entered empty.	System	30 Apr 2021 19:05:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 20:25:49
User entered empty.	System	30 Apr 2021 19:05:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 20:25:49
User entered empty.	System	30 Apr 2021 19:05:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 13:48:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 13:48:33
Data point term sent to Coder	System	30 Apr 2021 19:11:34
User entered 'Enoxaparin'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Pulmonary Embolism'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '120'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 20:28:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Apr 2021 20:28:02
User entered 'twice daily (BID)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:28:02
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 19:11:09
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '01 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '04 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Apr 2021 20:28:02
User entered empty.	System	30 Apr 2021 19:11:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 20:28:02
User entered empty.	System	30 Apr 2021 19:11:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 20:28:02
User entered empty.	System	30 Apr 2021 19:11:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 19:38:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 19:38:12
Data point term sent to Coder	System	30 Apr 2021 19:12:35
User entered 'Amlodipine'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Hypertension'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '10'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'once daily (QD)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Oral (ORAL)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '27 Feb 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '09 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:11:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 19:11:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 19:11:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 19:11:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 19:13:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 19:13:08
Data point term sent to Coder	System	30 Apr 2021 19:12:35
User entered 'Metformin'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:15

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:15

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Diabetes Mellitus'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:15

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '500'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:15

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:15

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:15

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'once daily (QD)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:15

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:15

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Oral (ORAL)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:15

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:15

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '27 Feb 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:15

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:15

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:15

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '09 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:15

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:15

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 19:12:15

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 19:12:15

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 19:12:15

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 19:14:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 19:14:09
Data point term sent to Coder	System	30 Apr 2021 19:13:36
User entered 'Lisinopril'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Hypertension'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '10'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'once daily (QD)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Oral (ORAL)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '27 Feb 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '27 Feb 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:12:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 19:12:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 19:12:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 19:12:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 19:14:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 19:14:08
Data point term sent to Coder	System	30 Apr 2021 19:13:36
User entered 'Acetaminophen'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Lumbar back pain'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '650'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'as needed (PRN)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:26:10
User entered 'once daily (QD)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Oral (ORAL)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '28 Feb 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '09 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 20:26:10
User entered '1'	System	30 Apr 2021 19:13:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 20:26:10
User entered '1'	System	30 Apr 2021 19:13:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 20:26:10
User entered '804 (804)'	System	30 Apr 2021 19:13:09

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 15:48:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 15:48:07
Data point term sent to Coder	System	30 Apr 2021 19:14:43
User entered 'Lorazepam'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Agitation (related to Bipolar Disorder with Psychosis)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '2'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'as needed (PRN)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:26:17
User entered 'once daily (QD)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Oral (ORAL)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '01 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '02 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:13:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 20:26:17
User entered '1'	System	30 Apr 2021 19:13:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 20:26:17
User entered '1'	System	30 Apr 2021 19:13:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 20:26:17
User entered '804 (804)'	System	30 Apr 2021 19:13:45

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: BUTYROPHENONE DERIVATIVES, PRODUCT: HALOPERIDOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 13:52:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 13:52:36
Data point term sent to Coder	System	30 Apr 2021 19:14:43
User entered 'Haloperidol'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Bipolar Disorder with Psychosis'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '5'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'other (OTHER)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:26:29
User entered 'once daily (QD)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Every 12 hours' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:26:29
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Oral (ORAL)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '01 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '05 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 20:26:29
User entered '1'	System	30 Apr 2021 19:14:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 20:26:29
User entered '1'	System	30 Apr 2021 19:14:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 20:26:29
User entered '804 (804)'	System	30 Apr 2021 19:14:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 19:16:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 19:16:09
Data point term sent to Coder	System	30 Apr 2021 19:15:44
User entered 'Metoprolol'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Hypertension'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '25'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'once daily (QD)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Oral (ORAL)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '01 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '09 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:14:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 19:14:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 19:14:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 19:14:59

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOHEXOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 15:48:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 15:48:07
Data point term sent to Coder	System	30 Apr 2021 19:16:45
User entered 'Lohexol'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:15:52

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:15:52

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Contrast for CT'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:15:52

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '120'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:15:52

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'mL (mL)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:15:52

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:15:52

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'once (ONCE)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:15:52

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:15:52

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Intravenous (INTRAVENOUS)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:15:52

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:15:52

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '01 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:15:52

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:15:52

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:15:52

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '01 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:15:52

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:15:52

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 19:15:52

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 19:15:52

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 19:15:52

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: LITHIUM, PRODUCT: LITHIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 15:47:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 15:47:04
Data point term sent to Coder	System	30 Apr 2021 19:17:45
User entered 'Lithium'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:10

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:10

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Bipolar Disorder with Psychosis'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:10

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '300'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:10

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:10

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:10

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'twice daily (BID)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:28:50
User entered 'once daily (QD)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:10

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:10

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Oral (ORAL)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:10

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:10

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '01 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:10

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:10

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:10

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '09 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:10

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:10

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Apr 2021 20:28:50
User entered '1'	System	30 Apr 2021 19:17:10

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 19:17:10

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 19:17:10

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 17:01:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 17:01:06
Data point term sent to Coder	System	30 Apr 2021 19:17:46
User entered 'Trazodone'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Bipolar disorder with psychosis'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '50'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'once daily (QD)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Oral (ORAL)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '01 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '03 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:17:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 19:17:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 19:17:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 19:17:38

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 13:48:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 13:48:33
Data point term sent to Coder	System	30 Apr 2021 19:18:47
User entered 'Enoxaparin'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:18:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:18:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Pulmonary Embolism'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:18:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '135'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:18:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:18:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:18:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 20:29:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Apr 2021 20:29:06
User entered 'other (OTHER)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:29:06
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 19:18:39
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:18:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Every 12 hours' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:29:06
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:18:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:18:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:18:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '05 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:18:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:18:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:18:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '09 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:18:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:18:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 19:18:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 19:18:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 19:18:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 19:20:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 19:20:59
Data point term sent to Coder	System	30 Apr 2021 19:19:49
User entered 'Eliquis'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:19:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:19:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Pulmonary Embolism'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:19:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '5'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:19:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:19:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:19:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'once daily (QD)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:19:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:19:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Oral (ORAL)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:19:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:19:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '05 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:19:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:19:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:19:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '05 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:19:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:19:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 19:19:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 19:19:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 19:19:33

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 15:48:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 15:48:07
Data point term sent to Coder	System	30 Apr 2021 19:20:50
User entered 'Lorazepam'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:06

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:06

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Agitation (related to Bipolar Disorder with Psychosis)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:06

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '1'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:06

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:06

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:06

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 20:29:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Apr 2021 20:29:17
User entered 'other (OTHER)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:29:17
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 19:20:06
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:06

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Every 8 hours' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:29:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:06

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Intramuscular (INTRAMUSCULAR)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:06

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:06

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '06 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:06

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:06

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:06

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '06 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:06

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:06

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 19:20:06

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 19:20:06

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 19:20:06

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 19:22:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 19:22:01
Data point term sent to Coder	System	30 Apr 2021 19:20:50
User entered 'Lactated ringers'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Hydration'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '500'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'mL (mL)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 20:29:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Apr 2021 20:29:27
User entered 'once daily (QD)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:29:27
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 19:20:40
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Intravenous (INTRAVENOUS)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '06 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '06 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:20:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 20:29:27
User entered empty.	System	30 Apr 2021 19:20:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 20:29:27
User entered empty.	System	30 Apr 2021 19:20:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 20:29:27
User entered empty.	System	30 Apr 2021 19:20:40

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFECTIVES, ATC: ANTIBIOTICS, PRODUCT: ERYTHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 13:49:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 13:49:34
Data point term sent to Coder	System	30 Apr 2021 19:22:51
User entered 'Erythromycin'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:14

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:14

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Conjunctivitis'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:14

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '5'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:14

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:14

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:14

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 20:29:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Apr 2021 20:29:39
User entered 'once daily (QD)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:29:39
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 19:22:14
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:14

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:14

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Topical (TOPICAL)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:14

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:14

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '06 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:14

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:14

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:14

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	03 May 2021 19:29:34
	(b) (4)	
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	30 Apr 2021 20:29:39
User entered '09 Mar 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	30 Apr 2021 20:29:39
	(b) (4)	
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	30 Apr 2021 19:22:14
User entered '09 Mar 2011'	Jiamin Li (b) (4)	30 Apr 2021 19:22:14
	(b) (4)	

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:14

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 20:29:39
User entered empty.	System	30 Apr 2021 19:22:14

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 20:29:39
User entered empty.	System	30 Apr 2021 19:22:14

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 20:29:39
User entered empty.	System	30 Apr 2021 19:22:14

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: BUTYROPHENONE DERIVATIVES, PRODUCT: HALOPERIDOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 13:52:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 13:52:36
Data point term sent to Coder	System	30 Apr 2021 20:30:07
Data point term sent to Coder	System	30 Apr 2021 19:23:52
User entered 'Haloperidol'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:58

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:58

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Pyschosis (related to Bipolar Disorder)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:58

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '5'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:58

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:58

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:58

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 20:29:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Apr 2021 20:29:53
User entered 'other (OTHER)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:29:53
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 19:22:58
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:58

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Every 12 hours' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:29:53
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:58

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 20:29:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Apr 2021 20:29:53
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:29:53
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 19:22:58
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:58

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:58

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '06 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:58

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:58

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:58

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '07 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:58

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:22:58

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 19:22:58

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 19:22:58

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 19:22:58

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 16:27:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 16:27:02
Data point term sent to Coder	System	30 Apr 2021 20:30:07
Data point term sent to Coder	System	30 Apr 2021 19:23:54
User entered 'Lorazepam'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:23:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:23:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Agitation (related to Bipolar Disorder with Psychosis)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:23:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0.5'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:23:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:23:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:23:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 20:30:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Apr 2021 20:30:05
User entered 'once daily (QD)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:30:05
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 19:23:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:23:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:23:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 20:30:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Apr 2021 20:30:05
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:30:05
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 19:23:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:23:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:23:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '08 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:23:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:23:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:23:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '08 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:23:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:23:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 20:30:05
User entered empty.	System	30 Apr 2021 19:23:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 20:30:05
User entered empty.	System	30 Apr 2021 19:23:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 20:30:05
User entered empty.	System	30 Apr 2021 19:23:34

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: ANTICHOLINERGIC AGENTS, ATC: ETHERS OF TROPINE OR TROPINE DERIVATIVES, PRODUCT: BENZATROPINE, PRODUCTSYNONYM: BENZTROPINE [BENZATROPINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 21:42:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 21:42:03
Data point term sent to Coder	System	30 Apr 2021 20:31:08
Data point term sent to Coder	System	30 Apr 2021 19:32:58
Data point term sent to Coder	System	30 Apr 2021 19:24:54
User entered 'Benztropine'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:24:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:24:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'UPPER EXTREMITY TREMOR' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:32:13
User entered 'Tremors (related to Bipolar Disorder)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:24:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0.5'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:24:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:24:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:24:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 20:30:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Apr 2021 20:30:22
User entered 'other (OTHER)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:30:22
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 19:24:39
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:24:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Every 12 hours' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:30:22
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:24:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:30:22
User entered 'Intravenous (INTRAVENOUS)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:24:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:24:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '06 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:24:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:24:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:24:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '08 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:24:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 19:24:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 19:24:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 19:24:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 19:24:39

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 17:14:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 17:14:19
Data point term sent to Coder	System	30 Apr 2021 20:31:09
User entered 'Dexrose 5% - Lactated Ringers'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:02

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:02

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Hydration'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:02

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '1'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:02

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'IU (IU)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:02

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:02

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'once (ONCE)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:02

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:02

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Intravenous (INTRAVENOUS)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:02

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:02

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '08 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:02

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:02

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:02

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '08 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:02

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:02

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 20:31:02

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 20:31:02

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 20:31:02

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 17:03:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 17:03:10
Data point term sent to Coder	System	30 Apr 2021 20:32:09
User entered 'Vancomycin'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:28

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:28

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Fever'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:28

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '1000'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:28

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:28

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:28

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'once daily (QD)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:28

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:28

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Intravenous (INTRAVENOUS)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:28

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:28

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:45

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '09 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:28

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '0'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:28

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:28

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '09 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:28

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:31:28

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 20:31:28

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 20:31:28

US3702046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 20:31:28

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:19:45

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:05:48
User signature succeeded.	Kristen Marks (b) (4)	03 May 2021 19:29:34
Signature has been broken.	Jiamin Li (b) (4)	30 Apr 2021 20:26:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	30 Apr 2021 20:26:52
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:35:13
User entered 'No (N)'	Jiamin Li (b) (4)	17 Mar 2021 20:04:33

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:19:45

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '01 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:27:04

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'CT Scan'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:27:04

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Adverse Event (AE)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:27:04

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:19:45

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:27:04

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:19:45

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '26 Feb 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:32:08

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'HEAD CTS and CXR'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:32:08

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Adverse Event (AE)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:32:08

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:19:45

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:32:08

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:19:45

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '01 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:32:20

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'CT Angiogram'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:32:20

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Adverse Event (AE)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:32:20

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:19:45

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:32:20

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:19:45

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '05 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:32:47

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'transesophageal echocardiogram'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:32:47

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Adverse Event (AE)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:32:47

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:19:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:32:47

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:19:45

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '05 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:32:58

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Duplex Study'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:32:58

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Adverse Event (AE)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:32:58

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:19:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:32:58

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:19:45

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '08 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:33:11

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Chest X-RAY'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:33:11

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Adverse Event (AE)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:33:11

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:19:45

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:33:11

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:19:45

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '08 Mar 2021'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:34:08

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:19:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Urine culture'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:34:08

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:19:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered 'Adverse Event (AE)'	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:34:08

US3702046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:19:45

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered empty.	Jiamin Li (b) (4) (b) (4)	30 Apr 2021 20:34:08

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'USA-US133-2021-MRNA-1273-P301000005'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'Yes (Y)'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'Yes (Y)'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:38:33
User entered 'Yes (Y)'	System	30 Apr 2021 18:54:20
Un-reviewed for Safety.	System	30 Apr 2021 18:49:09
User entered 'No (N)'	System	30 Apr 2021 18:49:09
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'Yes (Y)'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:38:33
User entered 'Yes (Y)'	System	30 Apr 2021 18:50:20
Un-reviewed for Safety.	System	30 Apr 2021 18:49:09
User entered 'No (N)'	System	30 Apr 2021 18:49:09
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'Yes (Y)'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'No (N)'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'No (N)'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'No (N)'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'Kristen'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'Marks'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered '525 East 68th Street'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'New York'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'NY'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered '10065'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:38:33
User entered 'US'	System	30 Apr 2021 18:14:17

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	03 May 2021 14:38:59
User entered '1'	System	30 Apr 2021 18:14:17

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'USA-US133-2021-MRNA-1273-P301000005'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'Yes (Y)'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'Yes (Y)'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:38:33
User entered 'Yes (Y)'	System	30 Apr 2021 18:54:20
Un-reviewed for Safety.	System	30 Apr 2021 18:49:09
User entered 'No (N)'	System	30 Apr 2021 18:49:09
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'Yes (Y)'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:38:33
User entered 'Yes (Y)'	System	30 Apr 2021 18:50:20
Un-reviewed for Safety.	System	30 Apr 2021 18:49:09
User entered 'No (N)'	System	30 Apr 2021 18:49:09
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'Yes (Y)'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'No (N)'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'No (N)'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'No (N)'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'Kristen'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'Marks'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered '525 East 68th Street'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'New York'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'NY'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered '10065'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:38:33
User entered 'US'	System	30 Apr 2021 18:14:17

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	03 May 2021 14:38:59
User entered '1'	System	30 Apr 2021 18:14:17

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:19:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '30/Apr/2021 14:14'	System	30 Apr 2021 18:14:17

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:19:45

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)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:38:33
User entered 'I'	(b) (4), (b) (6)	30 Apr 2021 18:14:17

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'USA-US133-2021-MRNA-1273-P301000005'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'Yes (Y)'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'Yes (Y)'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:38:33
User entered 'Yes (Y)'	System	30 Apr 2021 18:54:20
Un-reviewed for Safety.	System	30 Apr 2021 18:49:09
User entered 'No (N)'	System	30 Apr 2021 18:49:09
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'Yes (Y)'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:38:33
User entered 'Yes (Y)'	System	30 Apr 2021 18:50:20
Un-reviewed for Safety.	System	30 Apr 2021 18:49:09
User entered 'No (N)'	System	30 Apr 2021 18:49:09
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'Yes (Y)'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'No (N)'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'No (N)'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'No (N)'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'Kristen'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'Marks'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered '525 East 68th Street'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'New York'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered 'NY'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:14:10
User entered '10065'	System	30 Apr 2021 18:13:36

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 14:38:33
User entered 'US'	System	30 Apr 2021 18:14:17

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	03 May 2021 14:38:59
User entered '1'	System	30 Apr 2021 18:14:17

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:19:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	03 May 2021 19:29:34
User entered '03/May/2021 10:38'	System	03 May 2021 14:38:59

US3702046

Folder: SAE USA-US133-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:19:45

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)	03 May 2021 19:29:34
User entered 'I'	(b) (4), (b) (6)	03 May 2021 14:38:59